ALGO® 5
Newborn Hearing Screener

User Manual

natus®

P/N 000737J

© 2011 Natus Medical Incorporated

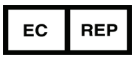
All rights reserved.

Distribution of contents to persons other than customers of Natus is strictly prohibited.
The content of this manual may change without notice.

ALGO® is a registered trademark of Natus Medical Incorporated. Microsoft, Windows, and the Windows logo are trademarks or registered trademarks of Microsoft Corporation. Adobe, OZ, HiTrack and all other trademarks are the property of their respective holders.

Natus Medical Incorporated
One Bio-logic Plaza
Mundelein, IL 60060 USA
Telephone +1 (650) 802-0400
Fax +1 (650) 802-0401

www.natus.com



Natus Europe GmbH
Bärmannstrasse 38
D-81245 München
Germany

CE 0086

CONFIDENTIAL
PROPERTY OF NATUS MEDICAL INCORPORATED MEDICAL INCORPORATED
ALL RIGHTS RESERVED

Table of Contents

Table of Contents v

System Description 1

Intended Use 1

Safety Information 2

Explanation of Terminology 2

Explanation of Symbols 2

Electrical Safety 3

Electromagnetic Emissions 3

Precautionary Information 7

Overview of the ALGO Screening Technology 9

Pass/Refer Criteria 9

Screener Components and Accessories 10

Screening Module 10

Cable Assemblies 12

Screening Station (Cart) 15

ALGO Screening Supplies 16

User Interface 17

Interface for the ALGO Screener 17

Note on Screen Appearance 17

Login Window 18

Main Window 18

Patient Data Window 20

Risk Factors Window 21

Screening Method Selection Window 22

Baby Preparation Window 23

Screening Window 24

Preferences Window 25

Equipment Check Window 26

audble® Data Management Window 27

Help Windows 28

Using the System 28

Operating Instructions 31

Overview of Screening Procedure 31

Selecting a Baby 32

Important Notes about Proper Baby Selection 33

Setting Up the Screener *33*
Starting Up the Screener 34
Enter Patient Information 35
Preparing the Baby for Screening *39*
Running the Screening Procedure *45*
Right/Left Simultaneous Screening Method 46
Pausing a Screening 49
Right/Left Sequential Screening Method 50
Single-Ear Screening Method 51
Cleanup *51*
Proper Shutdown Procedures *53*
Cable Storage *54*

Troubleshooting 55
Using Online Help *55*
Help Topics: 55
Using Help 56
Artifact Rejection Systems *56*
Impedance and Sensor Problems *57*
Check Screener 57
Check Environment 59
Check Baby 59
Prepping Techniques *60*
Reprep Method 61
Ambient Interference *63*
Check Screener 63
Check Environment 64
Check Baby 64
Myogenic Interference *65*
Check Screener 65
Perform an Impedance Check 65
Check Environment 66
Check Baby 67
Understanding a “REFER” result *67*
Check Screener 68
Check Environment 68
Check Baby 69
Error Messages and System Failure *69*
Printer Error 69
System Error 69
Time Limit 70

 © 2011 Natus Medical Incorporated

Equipment Check *70*
Artifact Check 72
Acoustic Check 73
Impedance Check 73
Database Corruption and Improper Shutdown Dialogs *73*
Corruption issues 75
Subsequent uses of the device 76
Update and Backup procedures 77

Service and Maintenance 79
Cleaning the Screener *79*
Inspecting Accessory Parts *80*
Loading Printer Labels *81*
Correcting a Printer Jam *82*
Technical Service and Calibration *82*
ALGO Screener Calibration Requirements 82
Calibration Considerations 83
Corrective Service/Maintenance 83

Preferences and Profiles 85
ALGO 5 Preferences *86*
Common Settings 86
Screening Options 87
User and Session Management 88
Printer Settings 89
Overall Result Computation 89
audble Data Management Preferences *91*
Single Patient Layout Editor 91
Risk Factor Editor 95
Report Template Editor 97
Pick List Editor 100
Export Format and Network Settings 101
Field Label Editor *102*
User Management *103*
Create new user 104
Edit User 104
Activate or Deactivate User 105
Profile Manager *105*
Create New Profile 105
Edit Profiles 106
System Control *106*
Label Printer 107
Letter Printer 107

Date and Time Control . . . 107
Wireless LAN . . . 108
System Info . . . 109
Update . . . 110
Backup . . . 110
Restore . . . 111
Archive Data . . . 111

audble® Data Management . . . 115
Note on Configuration . . . 115
Example Data . . . 115
Finding and Displaying Patient Records . . . 115
Editing Patient Records . . . 117
Adding Patient Records . . . 118
Screen Baby . . . 118
Exporting Data . . . 118
Importing Data . . . 120
Resolving Import Conflicts . . . 121
Selecting and Printing Letters and Reports . . . 122
Printing Labels . . . 123
Printing Letters and Reports . . . 123
Patients Reports and Letters . . . 123
Statistics Reports . . . 123
Customizing Data Display . . . 124

Appendix 1 . . . 125
Storing ALGO 5 Screener Cables . . . 125
High Risk Indicators . . . 126
Specifications . . . 126
Sweep Rates . . . 126
Power Supply . . . 126
Classifications . . . 127
Glossary . . . 127

Appendix 2 . . . 129
ALGO 5 Software License Agreement . . . 129

List of Figures . . . 133

Index . . . 135

 © 2011 Natus Medical Incorporated

System Description

The ALGO® 5 Newborn Hearing Screener User Manual is designed to educate you on the proper and safe use of the product. This chapter covers several important introductory topics, including:

- Intended use: see “Intended Use” on page 1
- Safety information: see “Safety Information” on page 2
- Overview of the ALGO screening technology: see “Overview of the ALGO Screening Technology” on page 9
- Screener components and accessories: see “Screener Components and Accessories” on page 10
- User interface: see “User Interface” on page 17
- Using the system: see “Using the System” on page 28

For installation and assembly information, see the Service Manual and accessory part installation notes.

Intended Use

The ALGO 5 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR® (Automated Auditory Brainstem Response) technology. The ALGO 5 also includes Natus Medical’s audble® Data Management software pre-installed.

The screener is intended for babies between the ages of 34 weeks (gestational age) and six months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening.

The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good health. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother’s bedside, audiology suite, outpatient clinic, or doctor’s office.

Contraindications for Use:

Screening an infant with known neurologic conditions should be done only under well-informed medical and/or audiological supervision.

© 2011 Natus Medical Incorporated

Safety Information

Explanation of Terminology

This manual presents three types of precautionary information. The three types of statements carry equal weight; that is, they are of equal importance to the safe and effective use of the device. Each statement is categorized by using an introductory word in boldface as follows:

⚠ **WARNING:** Identifies conditions or practices that might present danger or possible injury to the patient and/or user.

IMPORTANT: An instruction provided to help ensure correct clinical results.

CAUTION: An instruction that, if not followed, can result in a condition that could damage the screening device.

Other explanatory information is highlighted with the word **Note**. Information in this category is not considered precautionary.

Note: Background information provided to clarify a particular step or procedure.

Explanation of Symbols

Symbol	Meaning
	Attention, consult product documentation
	Consult instructions for use
	Type BF rate for patient-applied parts
	Power
	WEEE Directive (Waste from Electrical and Electronic Equipment Directive) Symbol - Product should not be disposed of in normal waste
	Manufacturer
	Fuse
	Direct current
	AC/DC adapter
	Serial port

 © 2011 Natus Medical Incorporated

Electrical Safety

The ALGO® 5 hearing screener is a Class A device (CISPR Classification), which is allowed in domestic establishments when used under the jurisdiction of a health care professional.

This device may cause radio interference, in which case adequate measures may be required to prevent interference.

The ALGO® 5 screener complies with the following electrical safety standards:

- UL2601-1
- CAN/CSA-C22.2 601-1
- EN60601-1
- EN60601-1-2
- EN60601-1-4
- Electrical rating Class I, Type BF

Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The ALGO 5 is intended for use in the electromagnetic environment specified below. The customer or the user of the ALGO 5 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ALGO 5 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ALGO 5 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating ALGO 5 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The ALGO 5 is intended for use in the electromagnetic environment specified below. The customer or the user of the ALGO 5 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Or a batt ± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	100% dip 60% dip 30% dip 100% dip	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ALGO 5 requires continued operation during power mains interruptions, it is recommended that the ALGO 5 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

 © 2011 Natus Medical Incorporated

Guidance and manufacturer's declaration - electromagnetic immunity			
The ALGO 5 is intended for use in the electromagnetic environment specified below. The customer or the user of the ALGO 5 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ALGO 5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environmnet due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the ALGO 5 is used exceeds the applicable RF compliance level above, the ALGO 5 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ALGO 5.

[b] Over the frequency range 150 kHz to 80 MHz, field strenghts should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ALGO 5

The ALGO 5 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ALGO 5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ALGO 5 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to the frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0.12	0.12	0.20
0,1	0.37	0.37	0.63
1	1.17	1.17	2.0
10	3.69	3.69	6.32
100	11.67	11.67	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

 © 2011 Natus Medical Incorporated

Precautionary Information

Read all sections of this user manual carefully before attempting a hearing screening with an infant.

IMPORTANT: Incorrect use of the screener and its accessories, or the use of parts and accessories that are not manufactured or supplied by Natus Medical Incorporated can lead to incorrect results.

⚠ **WARNING:** Do not use your screener if there is any suspicion that it is not functioning properly, or if any parts appear damaged. Contact Natus Medical Technical Service or your authorized service representative.

⚠ **WARNING:** Any misuse of the earphones or the earphone cable (that is, any use other than that described in this manual) may result in screening at unknown and uncontrolled decibel levels.

⚠ **WARNING:** Do not remove the computer from the screening system unless your service representative specifically instructs you to do so.There are no user-serviceable parts inside the computer aside from replacement of the RTC Battery. Installation, modification, or replacement of any computer accessories, circuit cards, components, or alteration of the CMOS configuration memory may compromise the safe and effective operation of this device and will void the warranty.

CAUTION: **There is no user access to the computer operating system.** Never attempt to load software into the system that has not been supplied or approved by Natus Medical. Attempting to load any software, computer accessory, or other medical device that has not been provided or approved by Natus Medical is expressly prohibited and will void the warranty.

CAUTION: The label printer with the ALGO 5 screener uses a thermal print mechanism. This technique avoids the use of inks and ribbons; however, because the paper is heat-sensitive, it is possible for a label to darken if exposed to high heat or very bright light for an extended period of time. It is also possible for certain plasticizers in some plastic binders to cause a reaction which results in the image fading over time. **Care should be taken by the institution to back up screening results to ensure long-term record retention.**

⚠ **WARNING:** Verify the maximum load for all multiple portable socket-outlets does not exceed 600VA.

⚠ **WARNING:** Do not place multiple portable socket-outlets on the floor.

⚠ **WARNING:** Never connect an extension cord to the multiple portable socket-outlets.

⚠ **WARNING:** Do not use the multiple portable socket-outlets to power any equipment that is not a part of the ALGO 5 system. Adding other equipment may increase the current amount of leakage and exceed the safety limit.

⚠ **WARNING:** Do not connect non-medical electrical equipment directly to a wall outlet if the Natus ALGO 5 system is using a multiple portable socket-outlet with a separating iso-transformer. The additional equipment may increase the current amount of leakage and exceed the safety limit.

⚠ **WARNING:** Do not connect other equipment to the ALGO 5 system that is not part of the system. The additional equipment may increase the current amount of leakage and exceed the safety limit.

CAUTION: Always power off the device via the computer menu selections available. Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown. The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate." Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to Shutdown Procedures on Page 49.

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to Shutdown Procedures on Page 49.

 © 2011 Natus Medical Incorporated

Overview of the ALGO Screening Technology

The ALGO screener delivers thousands of soft click sounds at 35 dB nHL ('normal hearing level' scale) to a newborn's ears through disposable earphones. Each click evokes a series of identifiable brain waves from a special area of the baby's brain called the auditory brainstem. This brain wave activity is called the auditory brainstem response (ABR). The ABR is the most accurate measure of auditory sensitivity in the newborn population.[1]

The instance in which the screener delivers a click and receives a response to that click is called a **sweep**. Sensors on the baby's skin pick up the brain wave signals and transmit the signals to the screener. Since these signals are very small compared to other electrical activity in a baby's brain, it is important to place the sensors correctly and ensure that the baby is sleeping quietly or is in a quiet state.

The screener uses advanced signal processing technology to separate the ABR waves from background noise and other brain activity. These brain waves are averaged and checked to see if they are consistent with a pattern called a template. The template is derived from ABRs of normal-hearing infants. The screener must detect the ABR waveform with high statistical confidence to determine that a response is present.

The screener's design offers simple user interaction with on-screen instructions. The screener is part of a mobile screening station and can be used easily at an infant's cribside. The included label printer automatically prints results on a self-adhesive label, which can be affixed directly in the medical chart. An optional letter printer can also be used to print patient results, reports, and letters. The screener can be operated by trained volunteers and other trained nonmedical personnel. Users can track screening data with the integrated ALGO audble® NHS Data Management System software. (See "audble® Data Management " on page 115)

Pass/Refer Criteria

During the screening process, the screener measures the probability of two conditions: a response-plus-noise condition (PASS) and a pure noise or no response condition (REFER). To grant a PASS or REFER result, the screener measures the probability that the infant's response is present.

Pass Condition:

The screener will generate a PASS result when it collects sufficient data to establish with >99% statistical confidence that an ABR signal is present and consistent with the template at a minimum of 1000 sweeps.

Refer Condition:

The screener will continue to collect data up to 15,000 sweeps. If it has not established with >99% statistical confidence that the ABR signal is present at 15,000 sweeps, the screener will generate a REFER result.

1. Jacobson J et al Jacobson J et al. (1990) Automated and conventional ABR screening techniques in high-risk infants. Journal of American Academy of Audiology, 1(4): 187–195.

Screener Components and Accessories

The screening system is made up of several primary components:

- Screening module with computer/monitor and keyboard
- Label printer
- Cable assemblies
- Screening station (cart) for component storage and transport
- Screening and accessory supplies

Screening Module

The screening module combines a computer with a cart. This cart contains a special set of customized electronic components that incorporate the AABR technology.

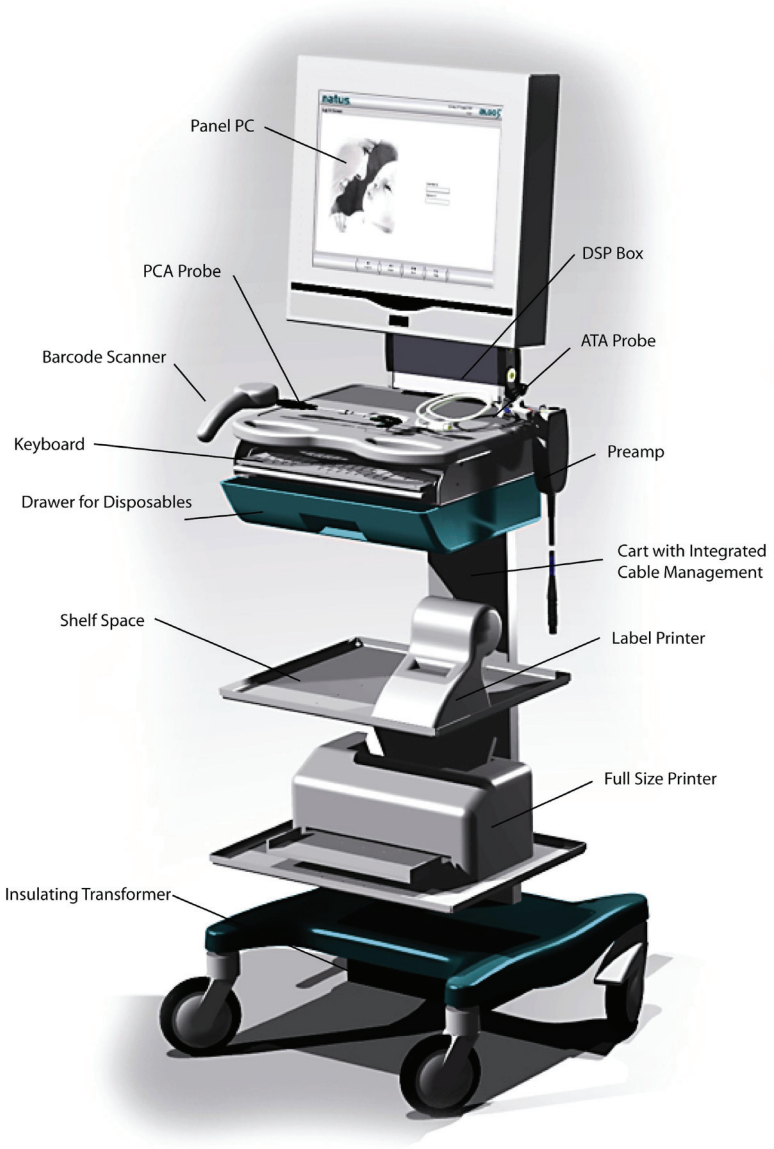
The monitor display presents windows containing command buttons, baby illustrations, instructions, screening parameters, and screening results. You operate the screener by using command buttons along with the keyboard, touch screen (if available), and/or pointing device to select and begin each procedure.

Results are recorded within the computer and can also be printed on a label or report by a printer. The screener preferences can be set to print the results onto a label automatically at the end of a test. A label printer is included as a standard part of the package; a letter-size printer for reports and letters is an optional addition.

You will find a CD ROM drive on your computer. The CD-R drive, or a USB flash drive, allows you to save a copy of the results as a computer file. The CD ROM drive also allows you to install Natus Medical-approved software updates.

 © 2011 Natus Medical Incorporated

Figure 1—Screening module and cart



Note: Controls for brightness, contrast, and color adjustment are adjusted by pressing the “Menu” button on the front of the monitor display. Use the arrow buttons, along with the “SEL(ect)” and “Exit” buttons to cycle through the menu choices. Adjust these controls to improve display screen visibility, if desired.

Note: Location of controls may differ from the description above, depending on the computer used.

Cable Assemblies

The **earphone cable** (also known as the Acoustic Transducer Assembly 5 or ATA 5) consists of two cables each with plastic transducer housings on one end that merge into a single cable. Each transducer housing holds a speaker to generate the click sounds and a microphone to listen for ambient noise.

The transducer housings fit into the earphones and are identified with red for the right ear and blue for the left ear.

Figure 2—Earphone (ATA) cable

The **sensor cable** includes three individual cables, each with a colored **clip** at one end, that merge into one cable before connecting to the preamplifier box.

CAUTION: Do not allow transducers to dangle from the screener, or to bang against the side of the cart. Never swing the earphone cable or strike the transducers against a hard surface. Shock to the transducers can result in damage to their sensitive acoustic components.

 © 2011 Natus Medical Incorporated

Figure 3—Sensor cable, also called the Patient Cable Assembly 5, or PCA 5

Both the earphone (ATA) cable and the sensor (PCA) cable plug into the **preamplifier cable** which plugs into the DSP box.

The clips attach to the sensors on the baby's skin and transmit the baby's brain wave signals back to the screener. When not in use, the preamplifier and sensor cable should be kept in the storage drawer, placed in the cable storage tray, or hung on the cable hanger at the back of the cart.

> **Note:** When not in use, transducers and the earphone cable can be stored in the drawer under the keyboard, hung on the forks at the back of the cart, or placed in the cable storage tray.

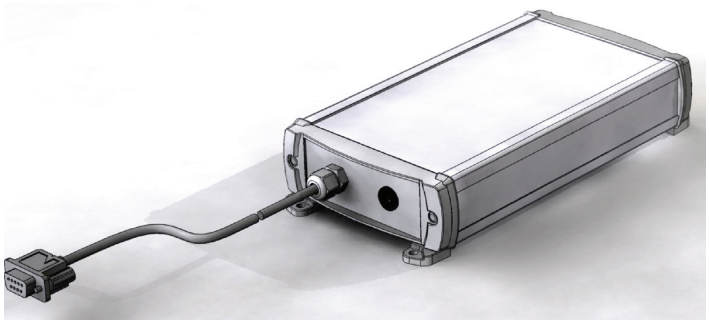
Figure 4—Preamp cable

CAUTION: When inserting the Preamp cable into the DSP, ensure that the alignment arrows match up to allow proper mating. The connection will not require force and an audible click will be heard with proper seating of the connector. Do not force the connection. Do not twist connection.

ALGO 5 software version 1.3 and later requires the use of a newer version preamp. Earlier version preamps will not function with these software versions. A warning message will appear. Please contact Natus Technical Service if this message appears.

 © 2011 Natus Medical Incorporated

Figure 5—DSP box



CAUTION: Before...

cycling the device power via the power switch on the column, or
unplugging the device, or
connecting or disconnecting cables, or
cleaning the device

...power off the device via the computer menu selections available. **Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown.**

The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate." Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to "Proper Shutdown Procedures" on page 53.

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to "Proper Shutdown Procedures" on page 53.

Screening Station (Cart)

The screening module is attached to a rolling cart used to transport and store the equipment. The cart brings the screener to the level of the infant's bassinet, thereby simplifying the preparation procedure.

The monitor height is adjustable. Loosen the two set screws on the attachment behind the monitor using the allen wrench included with your ALGO 5. Slide the monitor down, until it is at a comfortable viewing height, then tighten the knob to hold the monitor in place.

The cart includes a drawer under the monitor tray for storing the earphone cable and accessory components such as the user manual. Below the drawer are two storage shelves for keeping screening supplies. The cart also has a

cable hanger assembly for temporary storage of the preamplifier box and sensor cable and a cable storage tray.

ALGO Screening Supplies

The primary supplies used for screening include:

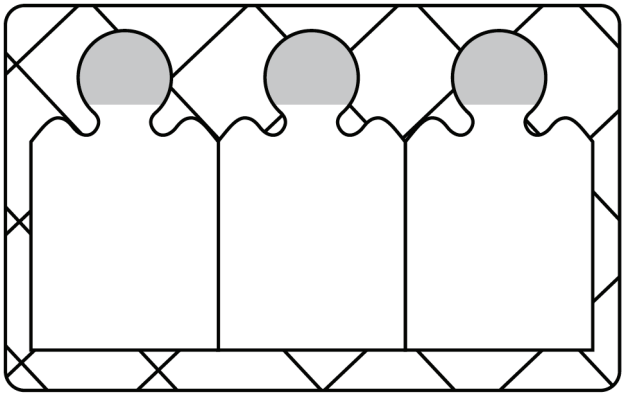
Jelly Tab™ sensors are electrodes that allow minute electrical signals of the auditory brainstem response to be transmitted across the infant's skin to the screener. The sensors are coated with a conductive hydrogel adhesive sealed under a plastic liner. The adhesive is designed especially for neonates.

Flexicoupler™ disposable earphones couple the acoustic clicks from the ATA to the ear, and they isolate the ear from noise in the environment. The earphones form a complete seal around the baby's ears, and connect to the screener through the earphone cable.

You can obtain prepping supplies, such as **NuPrep**™ gel, to remove surface oil or skin debris at the sensor sites on the baby. These products lower the electrical impedance of the baby's skin and improve the sensor connections.

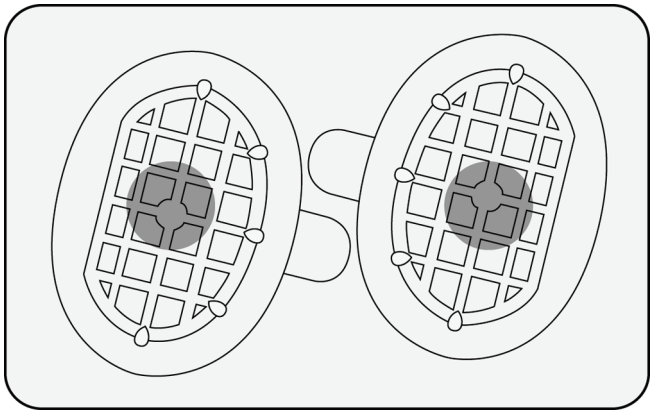
For more information, contact Natus Medical Customer Service or your authorized service representative.

Figure 6—Jelly Tab Sensors



 © 2011 Natus Medical Incorporated

Figure 7—Flexicoupler earphones



IMPORTANT: Use only Natus Medical-supplied screening supplies with the screener. The ALGO device and its screening supplies have been validated as a system, therefore Natus Medical cannot assure accurate results when the ALGO device is used with other manufacturer's supplies.

User Interface

Interface for the ALGO Screener

This section reviews the various windows that you will encounter as you operate the ALGO Newborn Hearing Screener. Included with each window description is a list of the command buttons associated with that window.

Command buttons are rectangular figures located at the bottom of the screener windows. The labels within each command button identify the action associated with that button when it is activated. You will use command buttons to navigate back and forth between various windows and to initiate actions essential to the completion of a screening.

The labels above the command button titles (e.g. F1, F9, F10) correspond to function keys found on the keyboard that perform the equivalent action of the command button. You may either use the touchpad to click a command button, touch screen (if available), or press the corresponding function key.

Note on Screen Appearance

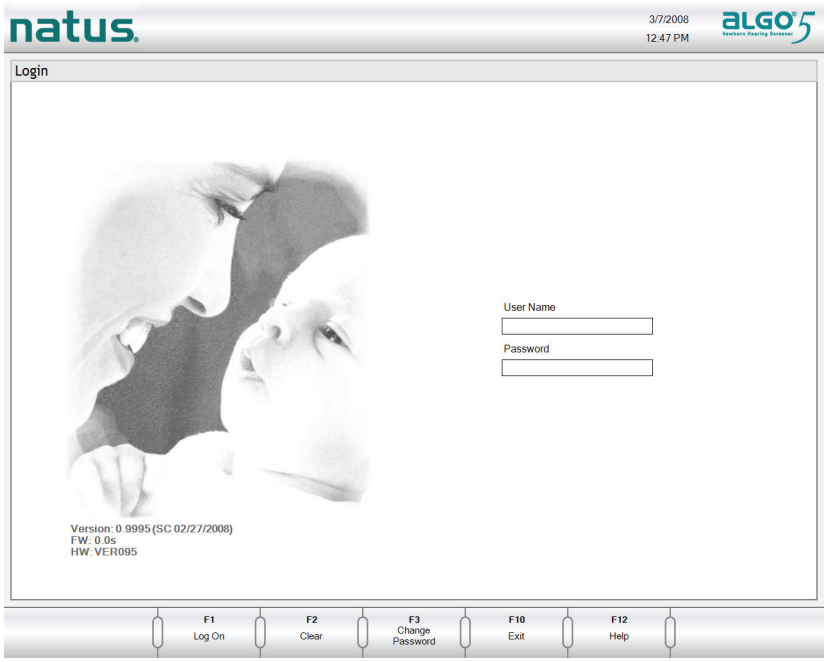
The screens shown in the following pages may look different than the screens on your particular device. Not all command buttons or onscreen choices (such as screening method or the list of risk factors) may be available, or may be different than the following screenshots illustrate.

The ALGO 5 is highly customizable. Your administrator may have set up preferences at the time of system configuration to modify the interface and adjust it to your institution's particular needs.

Login Window

Enter your user name and password into the fields in the Login window to access the ALGO 5 screening software.

Figure 8—Login window



Note: Screeners may or may not be required to login, depending on the preferences set up by the administrator at the time of software installation. If screener login is not required, this screen will show only the “Screen Baby,” “Equipment Check” and “Exit” functions. An administrator-level login and password is required to access the other administrator functions.

Main Window

The Main window allows you to start the screening process for a patient. It also gives you access to accessory features such as Data Management, Preferences, Equipment Check, and built-in Help.

 © 2011 Natus Medical Incorporated

Figure 9—Main window

Command Buttons:

Screen Baby (F1) Connects you to the Patient Data window, the first step in the screening process.

Data Management (F3) connects you to the audble window, where you can access the Audble data management software.

Preferences (F4) connects you to the Preferences window.

Equipment Check (F5) connects you to the Equipment Check window.

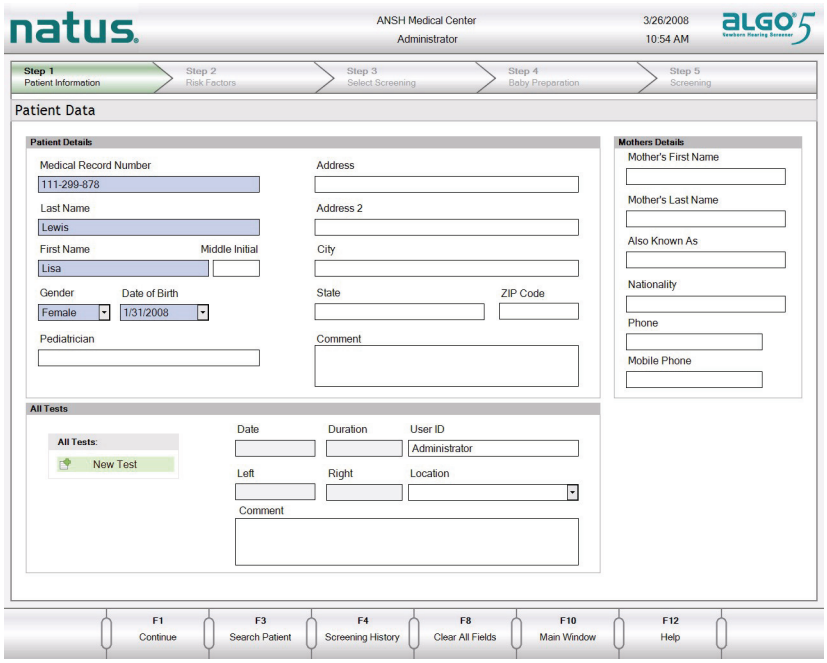
Exit (F10)

Help (F12) brings up the Help menu.

Patient Data Window

The Patient Data window allows you to enter required patient information, as mandated by your health care facility's protocol. (For more about this window, see "Enter Patient Information" on page 35.)

Figure 10—Patient Data window



Command Buttons:

Continue (F1) allows you to proceed to the next step in the screening process, once you have filled in the correct patient information.

Search Patient (F3) allows you use the patient's first or last name to search stored records.

Screening History (F4) displays previous test results for the selected patient.

Clear All Fields (F8) deletes all the information you have entered.

Main Window (F10) returns you to the main window.

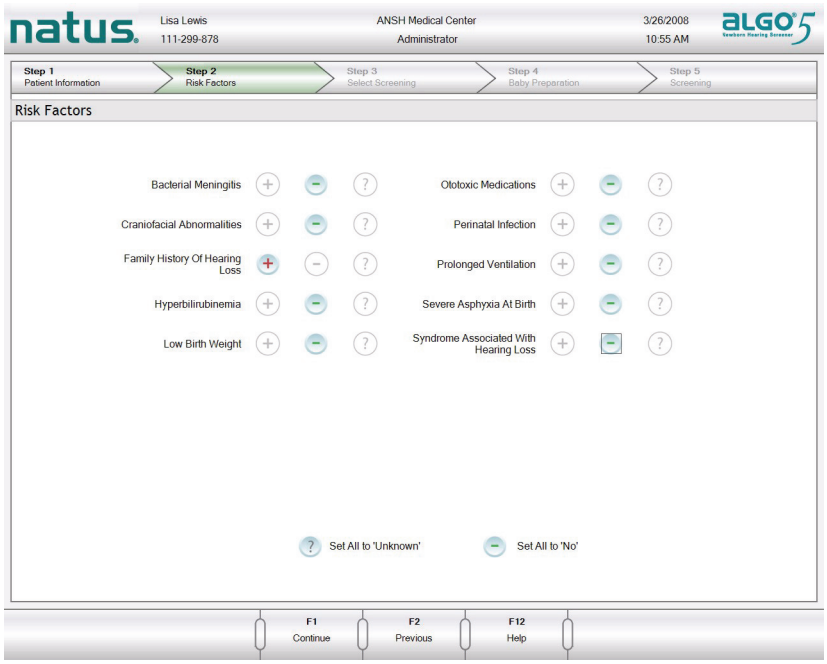
Help (F12) brings up the Help menu.

 © 2011 Natus Medical Incorporated

Risk Factors Window

The Risk Factors window allows you to indicate whether or not the listed risk factors apply to your patient, or whether these factors are unknown. (For more about this window, see “Enter the Risk Factors information” on page 37.)

Figure 11—Risk Factors



Command Buttons:

Continue (F1) allows you to proceed to the next step in the screening process, once you have filled in the correct patient information.

Previous (F2) allows you to go back to the previous step in the screening process.

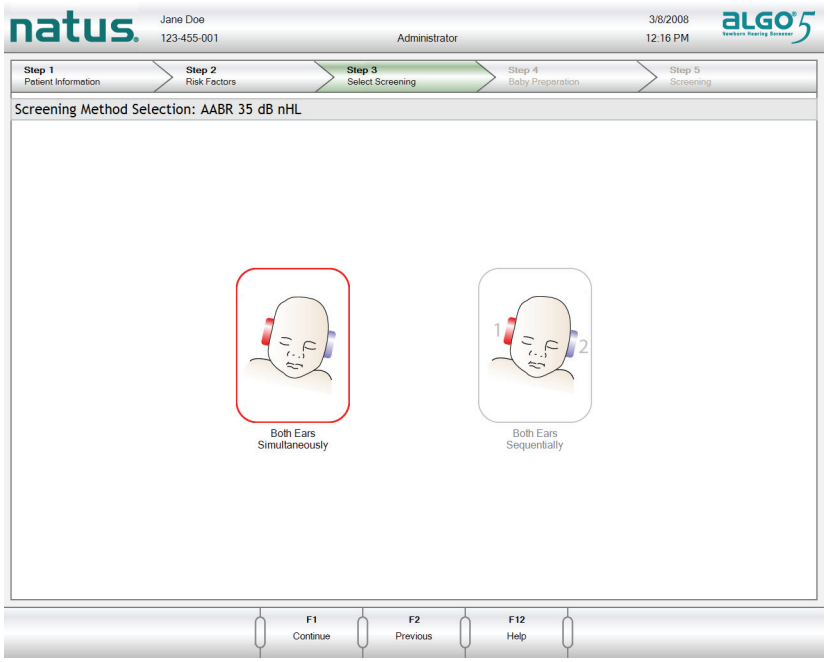
Help (F12) brings up the Help menu.

Screening Method Selection Window

The Screen Selection window allows you to choose the appropriate screening method for the baby. (For more about this window, see “Select a screening method” on page 38.)

Note: The screening method choices available to you may be different than those shown below, depending on your profile and how the software was configured by your system administrator at the time of installation.

Figure 12—Screening Method Selection window



Command Buttons:

Continue (F1) allows you to proceed to the next step in the screening process, once you have selected your screening method.

Previous (F2) takes you back to the Risk Factors window.

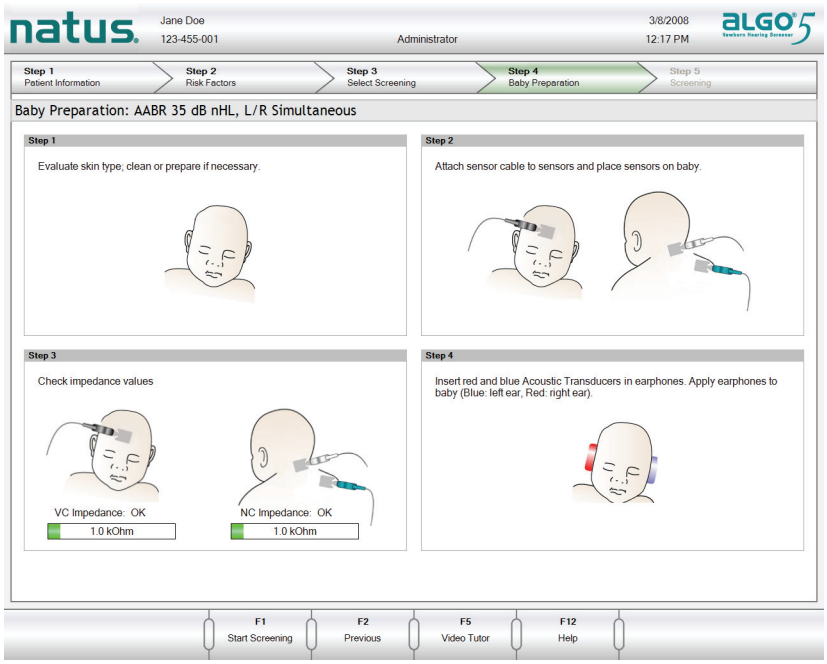
Help (F12) brings up the Help menu.

 © 2011 Natus Medical Incorporated

Baby Preparation Window

The Baby Preparation window allows you to review the necessary steps to prepare the baby for a screening and provides illustrations for the correct placement of Flexicoupler earphones and Jelly Tab sensors. (For more about this window, see “Preparing the Baby for Screening” on page 39.)

Figure 13—Baby Preparation window



Command Buttons:

Continue (F1) allows you to proceed to the next step in the screening process, once you have acceptable impedance values.

Previous (F2) take you back to the Screening Method Selection window.

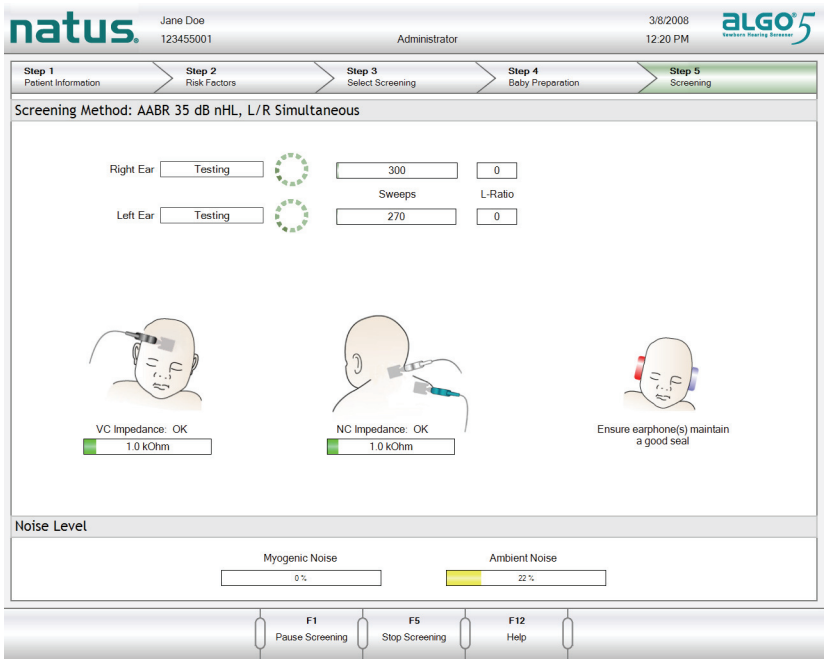
Video Tutor (F5) brings up a list of tutorial movies which demonstrate how to prep a baby, attach the Jelly Tab Sensors, or attach the Flexicouler Earphone.

Help (F12) brings up the Help Menu.

Screening Window

The Screening window gives you an overview of the screening in progress and allows you to monitor the impedance, myogenic, and ambient levels while the screener delivers soft clicks to the baby's ears. (For more about this window, see "Running the Screening Procedure" on page 45.)

Figure 14—Screening window



Command Buttons:

Start Screening (F1) allows you to begin the test.

Stop Screening (F5) allows you to stop the test.

Help (F12) brings up the Help Menu.

When the test is completed, the command button menu consists of:

Re-Screen Baby (F1) allows you to rescreen the same baby.

Screen Next Baby (F5) takes you to the Patient Data window, where you can start the screening process for your next patient.

Print Label (F6) prints the test results on a label.

Print Letter (F7) allows you to print a report of the test results.

Select and Print Report (F8) brings up a list of pre-formatted letters and reports that you can print.

For more information on printing labels, reports, and letters, see "Selecting and Printing Letters and Reports" on page 122.

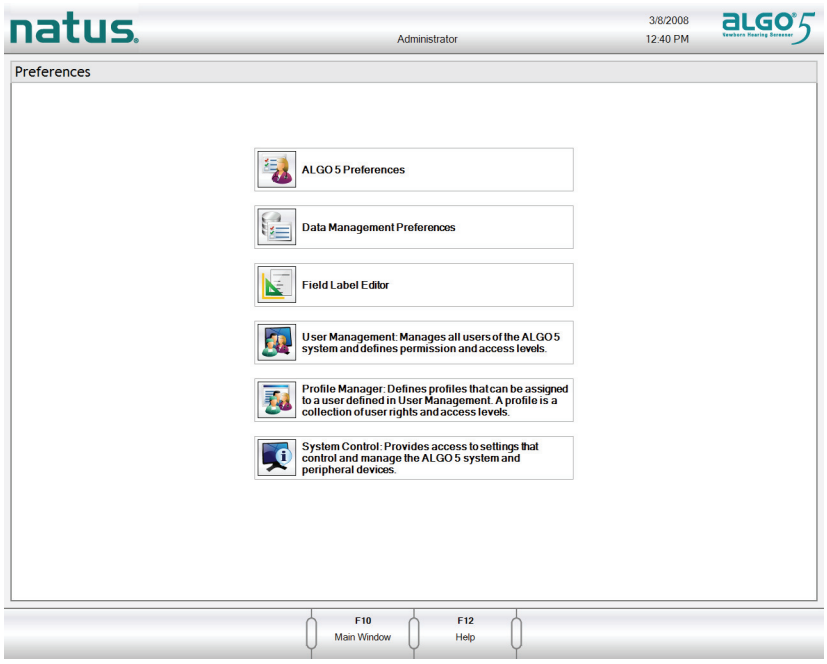
 © 2011 Natus Medical Incorporated

Preferences Window

The Preferences window gives you access to the ALGO 5 Preferences, Data Management Preferences, Field Label Editor, User Management, Profile Manager, and System Control.

Note: The options available to you may be different than those shown below, depending on your profile and how the software was configured by your system administrator at the time of installation.

Figure 15—Preferences window


natus
Administrator
3/8/2008
12:40 PM
ALGO 5
Preferences
ALGO 5 Preferences
Data Management Preferences
Field Label Editor
User Management: Manages all users of the ALGO 5 system and defines permission and access levels.
Profile Manager: Defines profiles that can be assigned to a user defined in User Management. A profile is a collection of user rights and access levels.
System Control: Provides access to settings that control and manage the ALGO 5 system and peripheral devices.
F10
Main Window
F12
Help

Command Buttons:

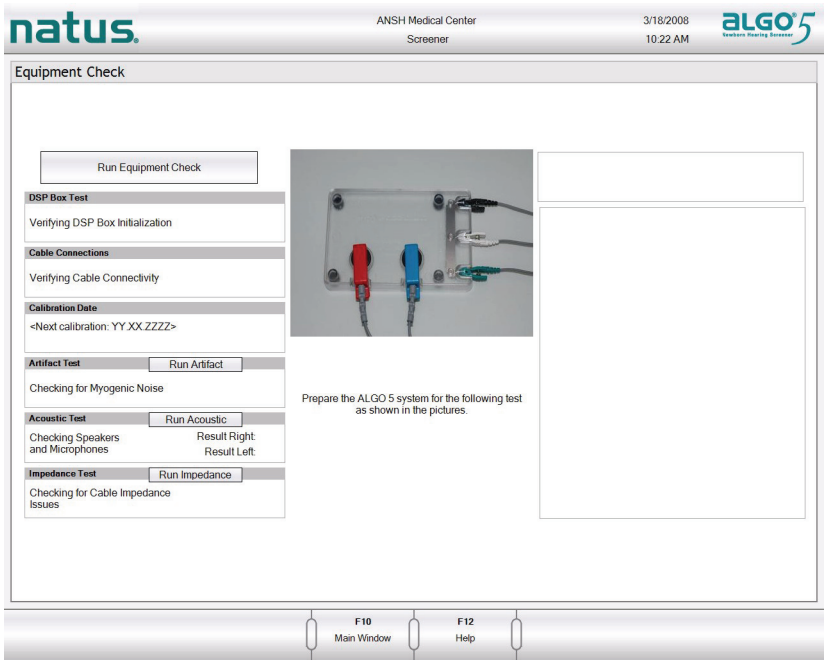
Main Window (F10) returns you to the main window.

Help (F12) brings up the Help menu.

Equipment Check Window

The Equipment Check window allows you to perform six inspections (baseboard, cable connection, calibration, impedance check, artifact check, and acoustic check) to help verify that the screener's hardware is operating correctly.

Figure 16—Equipment Check window



Command Buttons:

Main Window (F10) returns you to the main window.

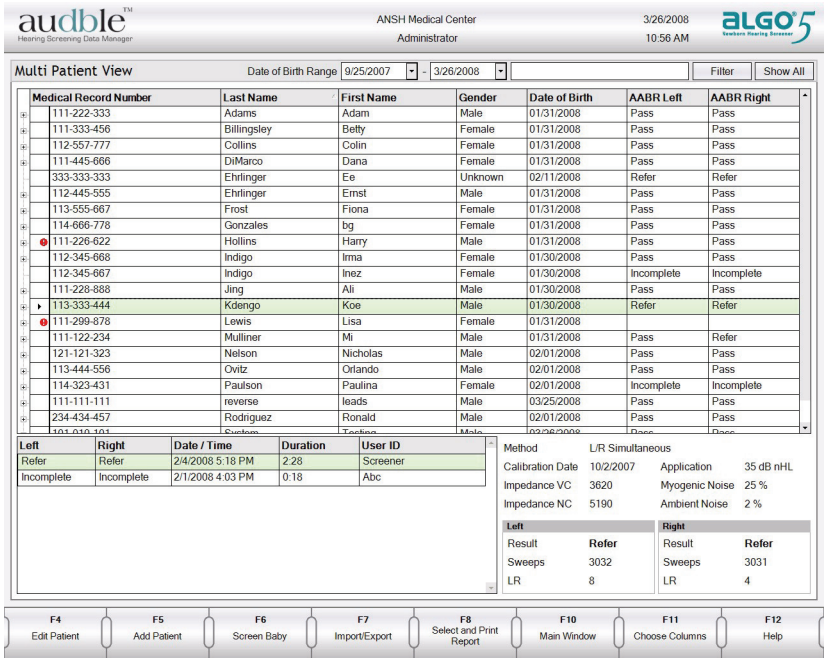
Help (F12) brings up the Help menu.

 © 2011 Natus Medical Incorporated

audble® Data Management Window

The Data Management window displays a list of patient and screening data stored in the screener, for a specified date range, medical record number, or patient name. (For more information about this window, see “audble® Data Management ” on page 115.)

Figure 17—audble Data Management window



Command Buttons:

Edit Patient (F4) allows you to edit the information in the highlighted individual patient record.

Add Patient (F5) allows you to manually add a new patient record.

Screen Baby (F6) allows you screen a baby whose patient record you are viewing.

Import/Export (F7) allows you to import records from or export records to a remote or local location.

Select and Print Report (F8) brings up a list of pre-formatted letters and reports that you can print. Both reports and letters can be customized by your administrator.

Main Window (F10) returns you to the main window.

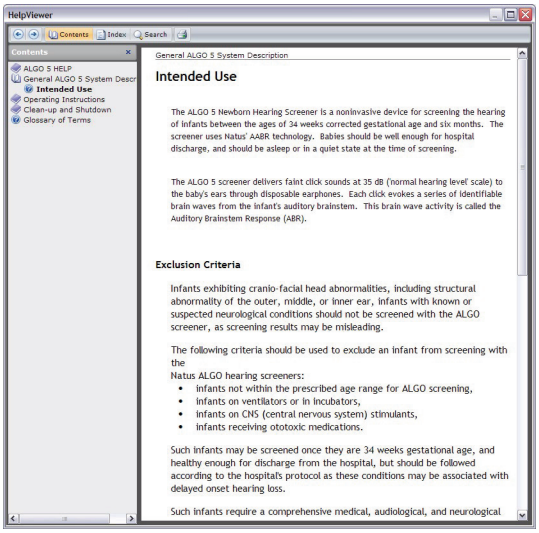
Choose Columns (F11) allows you to add, remove, or change the order of columns in the data display.

Help (F12) brings up the Help menu.

Help Windows

The Help Windows assist you with some aspects of screening a baby, such as correct sensor and earphone placement, and troubleshooting techniques.

Figure 18—Help Window


HelpViewer
Contents
Index
Search
Contents
ALGO 5 HELP
General ALGO 5 System Descr
Intended Use
Operating Instructions
Clean-up and Shutdown
Glossary of Terms
General ALGO 5 System Description
Intended Use
The ALGO 5 Newborn Hearing Screener is a noninvasive device for screening the hearing of infants between the ages of 34 weeks corrected gestational age and six months. The screener uses Natus' AABR technology. Babies should be well enough for hospital discharge, and should be asleep or in a quiet state at the time of screening.
The ALGO 5 screener delivers faint click sounds at 35 dB ('normal hearing level' scale) to the baby's ears through disposable earphones. Each click evokes a series of identifiable brain waves from the infant's auditory brainstem. This brain wave activity is called the Auditory Brainstem Response (ABR).
Exclusion Criteria
Infants exhibiting cranio-facial head abnormalities, including structural abnormality of the outer, middle, or inner ear, infants with known or suspected neurological conditions should not be screened with the ALGO screener, as screening results may be misleading.
The following criteria should be used to exclude an infant from screening with the
Natus ALGO hearing screeners:
infants not within the prescribed age range for ALGO screening,
infants on ventilators or in incubators,
infants on CNS (central nervous system) stimulants,
infants receiving ototoxic medications.
Such infants may be screened once they are 34 weeks gestational age, and healthy enough for discharge from the hospital, but should be followed according to the hospital's protocol as these conditions may be associated with delayed onset hearing loss.
Such infants require a comprehensive medical, audiological, and neurological

Note: The Help windows are separate “pop-up” windows that appear in front of the standard display windows.

Using the System

There are several options available to you for navigating the screen and activating your selection:

Function keys. One way to select and start most screener functions is by using the function key (e.g. F1, F9, F10) that corresponds to the appropriate command button. Pressing the function key automatically activates your selection.

Tab key. You can also press the tab key to move the cursor and highlight the appropriate command button located at the bottom of the screener windows. The enter key activates your selection. Also use the tab key to move to a new data-entry field on the display. Holding down the shift key while pressing the tab key enables you to move the cursor backwards through data-entry fields.

Touch screen. If a touch screen is available, you can make some selections by touching the screen to activate your selection.

Pointing device. You can also make selections with a pointing device (such as the trackpad device included on your keyboard, a mouse, or trackball), and a pointer selection button on the pointing device. The pointing device moves the cursor (or arrow) from one location to another.

After you relocate the cursor or arrow (using the pointing device) to the desired field or command button, you press the pointer selection button to activate the selection. You can use the pointer selection button to place check marks within certain boxes on the Patient Information and User Preferences Windows.

 © 2011 Natus Medical Incorporated

There may be two pointer selection buttons present. Use only the upper button or the left button with the screener; the lower button or right button has no function with the screener software.

Note: Neither the arrow keys nor the Enter key can be used to move the cursor through various data entry fields.

 © 2011 Natus Medical Incorporated

Operating Instructions

Testing a baby with the ALGO® 5 hearing screener involves:

- Selecting a baby: see “Selecting a Baby” on page 32
- Setting up the screener: see “Setting Up the Screener” on page 33
- Preparing the baby: see “Preparing the Baby for Screening” on page 39
- Running the screening and managing results: see “Running the Screening Procedure” on page 45
- Cleaning up and shutting down the screener: see “Cleanup” on page 51

Overview of Screening Procedure

The following is an overview of the screening procedure. For detailed information, read the remaining sections of this chapter.

1 **Select a baby appropriate for screening. (See** “Selecting a Baby” on page 32**.)**

2 **Set up the screener. (See** “Setting Up the Screener” on page 33**.)**
   - Enter patient information.
   - Select screening method.
     - R/L Simultaneous, right and left ears
     - R/L Sequential, right ear then left ear

3 **Prepare baby. (See** “Preparing the Baby for Screening” on page 39**.)**
   - Collect supplies.
   - Inspect cables for damage along the cables themselves, at both ends of each cable, or for any other visible signs of damage.
   - Connect the colored sensor clips to the sensors.
   - Identify and prepare sites for the three sensors
   - Place sensor/clips on the baby in the proper locations. Check impedance and adjust sensor connections, if necessary.
     - **Black** Clip to **Vertex** (center forehead, as high as possible)
     - **White** Clip to **Nape** (back of neck, centered)
     - **Green** Clip to **Common** (shoulder)
   - Attach transducers to earphones.
   - Place earphones on baby.
     - **Blue** transducer: **Left** ear
     - **Red** transducer: **Right** ear
   - Allow or assist baby to fall asleep (may include feeding).

4 **Run screening procedure. (See** “Running the Screening Procedure” on page 45**.)**

- Observe screening as necessary (may include troubleshooting).
- View results and printed label.
- Remove cable connections from baby.

5 **Clean up and shut down the machine using the proper shutdown procedures. (See** "Proper Shutdown Procedures" on page 49.**)**

- Do not turn off the computer using the Panel PC power switch nor turn off the system using the main power switch.
- Navigate device to main screen using "Main Window", then choose Exit > Power Off or Exit > Hibernate.
- Refer to page 49 for complete shut down instructions.

CAUTION: Always power off the device via the computer menu selections available. **Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown.** The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate.” Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to Shutdown Procedures on Page 49.

CAUTION: **Failure to shut down properly may lead to problems with the stability of the database containing patient data.** Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to Shutdown Procedures on Page 49.

Selecting a Baby

The most important factor in efficient screening is choosing a baby in a favorable state. Babies in the appropriate condition require less time to screen and are less likely to become fussy during the procedure. Below is a list of appropriate infant conditions.

- Term, healthy newborns
- NICU graduates, 34 weeks gestational age or older
- Newborns with normal outer ear anatomy and no obvious deformities of the head or neck
- Ready for discharge, or scheduled to go home within a few days
- Receiving no central nervous system (CNS) stimulants
- Sleeping or in a relaxed state (usually after a recent feeding)
- In an open crib

Note: Swaddling a baby prior to screening may help calm the baby thereby reducing myogenic interference.

 © 2011 Natus Medical Incorporated

Important Notes about Proper Baby Selection

Screening an infant in a less-than-appropriate state (awake or medically unstable) is not recommended and may increase screening time. Qualified medical, nursing, or audiological personnel must conduct any screening of such infants because troubleshooting during the screening may require professional assessment skills.

Also, please observe the following:

- Do not screen infants while they exhibit excessive movement as this may lead to high myogenic interference.
- Do not screen infants older than six months of age.
- The screener is not designed for infants with known absence or malformation of external, middle, or internal ear structures.
- The screener is not intended for neurodiagnostic procedures. Screening infants with known neurological conditions should be done only under well-informed medical and/or audiological supervision.
- Screening an infant in an incubator may result in increased interference, and may delay the results. It is recommended that screening be postponed until the infant is able to sleep in an open crib.

Setting Up the Screener

This section provides instructions for starting up the screener, selecting the screening method, and entering patient and user identification.

- **Do not** operate the screener in an environment where the screener continuously displays myogenic interference. Such interference may slow down or stop the screening and compromise the screener's performance or accuracy.
- **Do not** operate the screener if cardiac monitors or incubator fans in the near vicinity (or other equipment required for monitoring a very sick infant) are causing interference.
- **Do not** use the preamplifier in close proximity to electrical equipment or display monitors.

⚠ **WARNING:** Do not turn off medical equipment suspected of causing interference unless under the direct supervision of a physician or appropriate medical practitioner.

CAUTION: Grounding reliability can only be achieved when equipment is connected to a receptacle marked "hospital only" or "hospital grade" or equivalent.

Starting Up the Screener

1 Turn on the screener.

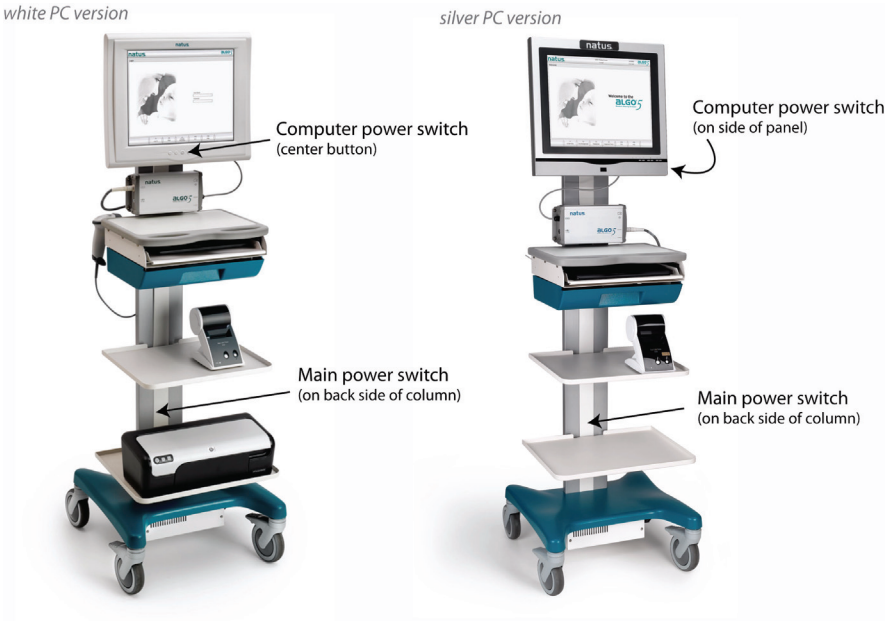
a First, push the main power switch at the back side of the column, to the on (I) position.

b Press and hold the computer power switch until the computer power light comes on. The screener begins its startup routine.

c Press the printer power switch. The printer power light turns on. The printer will also automatically turn on when printing the first label.

d After a series of startup messages, the Login window appears.

Figure 19—Power switches



CAUTION: Before...

cycling the device power via the power switch on the column, or
unplugging the device, or
connecting or disconnecting cables, or
cleaning the device

...power off the device via the computer menu selections available. **Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown.**

The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate." Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to "Proper Shutdown Procedures" on page 53.

 © 2011 Natus Medical Incorporated

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to "Proper Shutdown Procedures" on page 53.

⚠ **WARNING:** Do not turn on or turn off the screener while the screener is connected to a baby.

⚠ **WARNING:** **There is no user access to the computer operating system. Never attempt to load software into the system that has not been supplied or approved by Natus Medical. Attempting to load any software, computer accessory, or other medical device that has not been provided or approved by Natus Medical is expressly prohibited and will void the warranty.**

2 **Select the Screen Baby command button or F1.**

To screen a baby, select **Screen Baby (F1)**.

Enter Patient Information

The method you use to enter patient information will vary slightly and will depend on whether this is the first entry for a given medical record number, or whether there are already screening results stored for this baby. Detailed instructions for both methods follow the general information given below.

When entering patient information, press the tab key to move the cursor from field to field. To move the cursor backwards, press the tab key while holding down the shift key.

Note: You cannot use the arrow keys or the Enter key to move through fields in the Patient Data window.

Note: The cursor starts at the Medical Record Number field and moves from left to right. Tab order may have been custom configured by your System Administrator and may move in a manner more appropriate for your facility's workflow.

Required categories are indicated by colored fields. You must enter information in these fields to proceed with a screening. The factory default setting on the screener requires you to at least enter the patient medical record number, name, gender, and date of birth (DOB) in order for the screening to proceed. Additional categories may be required by your healthcare facility.

Entering Patient Information: Babies with No Previous Screening History

To enter information for a new patient:

1 **Type the patient's medical record number and press the tab key. Repeat for Last Name, First Name, Gender, and DOB fields.**

2 **Enter information into any other fields that are set as mandatory by the system administrator, or any additional information you desire to capture.**

Note: Click on the pull-down arrow in the date field to bring up an interactive calendar, or you can enter the date of birth using the keyboard (see note below).

Note: Although there is more than one acceptable method for entering the date of birth, only one format will appear on the display. You may enter the date of birth using slash marks (e.g., 7/30/01), using dashes (e.g., 7-30-01), or by spelling out the month (e.g., 30-Jul-01). Whichever you choose, it will always appear in the following format: 7/30/2007.

Note: Shortcuts: Entering "t" or [TAB] fills the DOB field with today's date. Entering "y" fills the DOB field with yesterday's date.

Note: A warning message appears if the date of birth entered is in the future or more than six months in the past.

3 **If you make a mistake, you can use the backspace key to delete the information in that particular field and re-enter the information.**

This will automatically replace the existing character.

You can delete the information in all fields at once by selecting **Clear All Entries (F8)**. This will delete all patient information and the cursor will remain in the field that it last occupied.

Note: The screener only saves patient information after you select **Continue**. If you turn off the screener before selecting **Continue**, the information you have entered will be lost.

Entering Patient Information: Babies with Previous Screening History

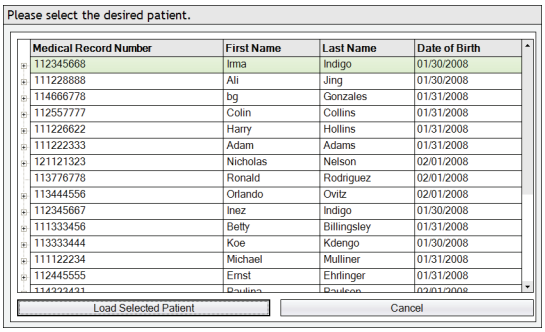
To enter information for an existing patient:

1 **Type the patient's medical record number and press the tab key.**

The following screen will appear:

 © 2011 Natus Medical Incorporated

Figure 20—Patient Selection window



2 Confirm that you are using the correct patient and medical record number.

If your patient is not listed, choose “no,” and check that you have entered the record number correctly. If you choose to use an existing patient, the screener will automatically fill in the patient information, as well as display the previous screening test results.

3 You can also choose Search Patient (F3) to load a patient based on any mandatory field partially filled in.

For example, typing an “A” into the Last Name field, then selecting Search Patient (F3) will bring up a list of patients whose last name begins with A; typing a “123” into the Medical Record Number field will bring up a list of patients whose MRN begins with 123.

Note: Any errors in patient names or medical record numbers can be resolved by the system administrator.

Note: The search for screening history data may take several seconds, and depends on the number of records contained in the file.

4 Review all information that automatically appears in the data fields; correct or update entries, as necessary.

(See “Entering Patient Information: Babies with No Previous Screening History” on page 36 for data entry instructions.)

5 If you need a printout of patient history, select Screening History (F4) from the Patient Data window. Then, choose Print Label (F6) from the Screening History window.

Note: The screener saves patient information if you select the **Continue (F1)** button. The screener will not save information if you turn off the screener before selecting **Continue**.

6 Enter the Risk Factors information

Complete the High Risk Indicators section by highlighting the **+** button for yes, **-** button for no, or the**?** button for unknown for each risk factor. You can also set all fields to Unknown or No using the buttons below the list.

For more information on risk factors, see “High Risk Indicators” on page 126.

Note: The High Risk Indicators section has a default setting of Unknown (**?**). Yes (**+**) indicates that the particular high risk indicator applies to the patient being screened. No (**-**) indicates that the particular high risk indicator does not apply to the patient being screened. Unknown (**?**) indicates that you are unable to determine if the particular high risk indicator applies to the patient **or** that the particular high-risk indicator is not applicable to your facility’s protocol.

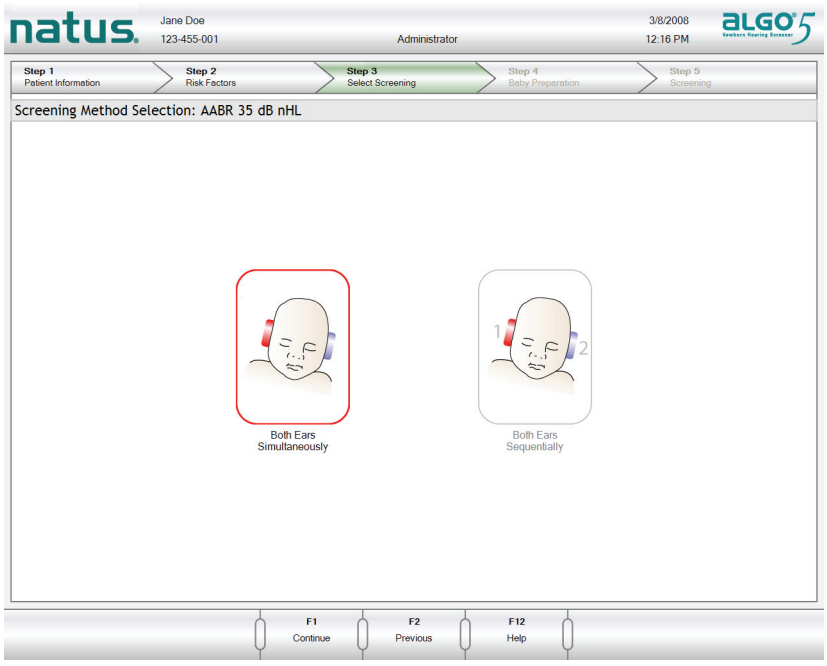
Note: Selecting Yes (**+**) for some risk factors will prevent a screening, depending on the settings in Risk Factor preferences.

7 Select a screening method

Choose the screening method advised by the protocol of your healthcare facility. For more information on screening methods, see “Determining Screening Application and Method” on page 39.

To indicate the default, a border appears around the box for the simultaneous screening method.

Figure 21—Screening Method Selection window



To use the default setting, select **Continue (F1)** to proceed to the Baby Preparation window. If you wish to select another screening method and/or application (if displayed):

a Use the pointing device to select the appropriate screening method.

 © 2011 Natus Medical Incorporated

b Once you choose the screening method, select **Continue (F1)** to proceed to the Baby Preparation window.

Note: You can select **Help (F12)** for more information on screening methods and applications.

Determining Screening Application and Method

The ALGO 5 screener is capable of offering the four different screening methods listed below.

Note: Current screening recommendations (see JCIH 2007 Position Statement) are for bilateral screening including rescreens. For this reason, single ear screening methods are hidden as the default. Administrators can enable these screening methods under ALGO 5 preferences.

Right/Left Simultaneous: This screening method is used to screen the right and the left ears at the same time. It is generally the fastest method if the baby is sleeping quietly.

Right/Left Sequential: This screening method is used to screen the right ear, then the left ear, one after the other. If a baby appears to be aroused by the simultaneous presentation of clicks to both ears, it may be faster to use the sequential method. Be sure to place the Flexicoupler earphones on both ears prior to screening.

Right Only: This screening method is used to screen the right ear only. This method may be used to rescreen an individual ear when local guidelines and protocols indicate this is an option.

Left Only: This screening method is used to screen the left ear only. This method may be used to rescreen an individual ear when local guidelines and protocols indicate this is an option.

Preparing the Baby for Screening

Proper preparation is essential to achieve accurate results. Become familiar with all instructions before preparing a baby for screening.

Note: Consult your healthcare facility's protocol for instructions on handling babies in the nursery.

The Baby Preparation window reviews the steps and provides illustrations for the correct placement of Flexicoupler earphones and Jelly Tab sensors.

1 Collect supplies.

- Flexicoupler disposable earphones (a pair)
- Jelly Tab sensors (a triplet)
- Prepping materials as needed (for example, soap, gauze sponge or washcloth, Nu Prep gel)

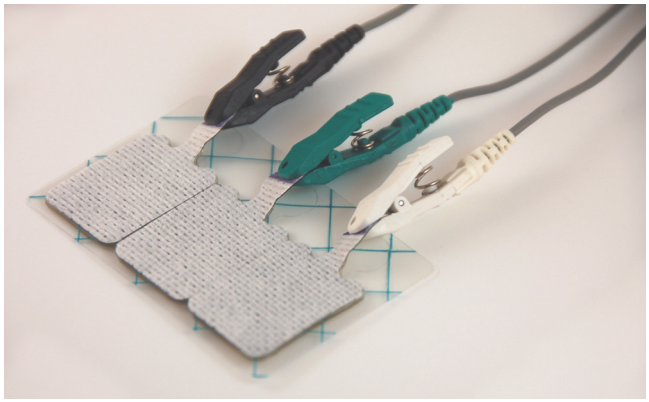
2 Attach sensor cable clips to sensors.

Squeeze the ends of the clip together so that the clip opens, and place on the colored tab portion of the sensor.

3 Place disposables and cables on the infant.

Place the PCA clips on the Jelly Tabs so that the clip has the wire on the side with the gel side of the electrode.

Figure 22—Electrodes



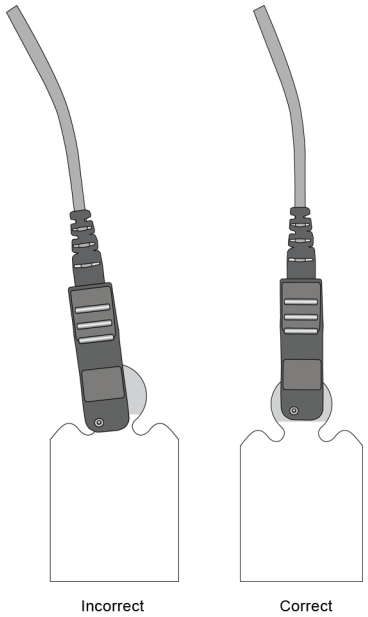
Note that this puts the shorter clip on the top. This may aid in reducing the strain on the electrode from the weight of the clip and may aid in signal conduction via a reduction in internal clip impedance.

IMPORTANT: Do not use a cable that is damaged or has exposed wires. Broken cables may cause excessive interference, screening delays, and inaccurate results.

CAUTION: Connect the sensor cable only to the purple colored tab section of the tab sensor. Do not allow the PCA clip to come in contact with the hydrogel portion of the tab sensor. Myogenic readings may be affected.

 © 2011 Natus Medical Incorporated

Figure 23—Clip placement



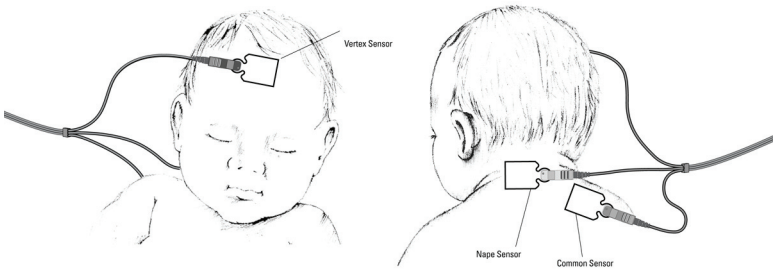
4 Identify three sites for sensor placement.

Correct sensor placement is critical. For better sensor adhesion, all tab sensors should be oriented in the same general direction toward the sensor cable. Use the sensor placement shown in the following figure. In the figures shown, all tab sensors are pointed to the baby's right side.

- Place nape sensor centered on back of neck, not on skull or back.
- The higher you place the vertex sensor on the forehead, the faster the screening will run. Be sure to center the sensor.
- Place common sensor on back of either shoulder.

IMPORTANT: Failure to place sensors in the recommended locations can result in significantly slower screening and increased refer rates.

Figure 24—Standard Sensor Placement
(All tabs on Jelly Tab Sensors are oriented to baby's right side)



5 Evaluate skin type; clean or prep if necessary.

If the skin appears oily or moist, gently wash each site with soap and water before attaching sensors. Remove all traces of soap.

IMPORTANT: Additional prepping may be required for some infants, for example, those with dry skin or body hair at sensor sites. These characteristics are associated with high impedance readings. For more information, see "Impedance and Sensor Problems" on page 57 and "Prepping Techniques" on page 60. You can also select **Help (F12)** for more details on impedance and sensor problems.

⚠ **WARNING:** Do not use soap or alcohol on an infant's skin unless permitted by your hospital's standard protocol.

6 Place sensor/clips over sites.

a Remove each sensor and attached clip from the plastic liner. It may be easier to remove the sensors on the left and right first, and then the sensor in the center.

b Place a sensor and colored clip directly over the appropriate site. Be sure to match the clip color to the correct sensor site.

- Sensor with **Black** clip to **Vertex** site (center forehead, as high as possible)
- Sensor with **White** clip to **Nape** site (center and back of neck)
- Sensor with **Green** clip to **Common** site (shoulder)

c Press gently and firmly to adhere the conductive hydrogel surface to the skin.

⚠ **WARNING:** Do not prep skin or apply sensors to damaged or compromised tissue or to babies with marked jaundice.

Note: Always handle the sensors by the non-adhesive tab only. The entire adhesive surface of a sensor is conductive and may become unusable (no longer conductive or sticky) with excessive or improper handling. As the electrode / PCA cable and the coupler / ATA cable assemblies are placed on the baby, **ensure that the ATA cable does not directly overlap any of the electrodes**. Simply making sure these ATA cables are not touching an electrode can aid in reducing interference during the test.

7 Check impedance readings.

As you attach the sensor cable to the sensors, the screener immediately provides two impedance readings and a sensor status message below the baby illustrations located in the middle of the screen.

 © 2011 Natus Medical Incorporated

If both impedance readings are less than 12 kOhms, no further handling of the sensors is required; the screener displays "Impedance OK." Proceed to place the earphones.

If an impedance reading is 12 kOhms or greater, the sensor on the baby illustration with the high impedance will flash red. Additionally, if the difference between the sensor pairs is above 2 kOhms, then the ALGO 5 will warn the user of an impedance mismatch. It is important that any impedance mismatch be as low as possible. A mismatch above 5 kOhms will cause the ALGO 5 to have the user lower the impedance difference before proceeding with a screen.

The screener will also display one or more of the following messages:

CHECK NAPE SENSOR

CHECK VERTEX SENSOR

CHECK COMMON SENSOR

CHECK EACH SENSOR

These events indicate that one or more of the sensor sites must be further prepped (with soap and water and/or other supplies). For instructions, see “Impedance and Sensor Problems” on page 57 and “Prepping Techniques” on page 60. You can also select **Help (F12)** on the Baby Preparation window for more details.

Note: If impedance readings range from 12 kOhms to 20 kOhms, gently lift sensors, apply a few drops of saline to the surface of each sensor, and gently press sensors to skin. If impedance readings show greater than 20 kOhms, re-prepping the sensor sites may be necessary. Refer to “Reprep Method” on page 61. The readings may drop to acceptable levels as moisture in the hydrogel surface of the sensor moves into the skin. The readings can also drop if you apply gentle but firm pressure to the sensor; however, do not continue to touch the sensors while screening is in progress.

Note: You cannot proceed with screening until the impedances are at acceptable levels.

Note: A reading of zero kOhm impedance may indicate a potential issue with the device. The ALGO 5 will warn you as to the occurrence of zero impedance. If this occurs during a screen, then the screen should be stopped and Natus Technical Service should be called.

Understanding Impedance

The screener provides two impedance readings.

Vertex Impedance: Impedance between the Vertex and Common sensors, in thousands of ohms (kOhms).

Nape Impedance: Impedance between the Nape and Common sensors, in thousands of ohms (kOhms).

These readings indicate how much the electrical conductivity of the skin is blocked by dry skin, debris, or oil. Prepping, which removes oil and debris, increases conductivity and decreases impedance.

Both impedance readings must be less than 12k (12,000) Ohms before the screener will begin testing. In general, the lower the impedance, the faster the screen will run.

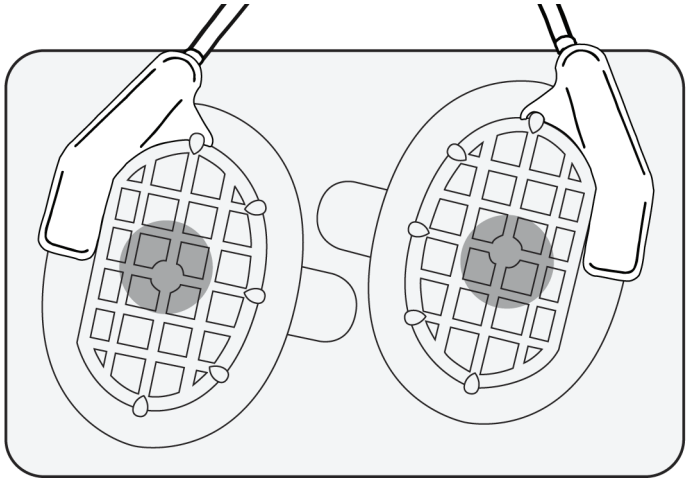
The difference in impedance between the Vertex-Common and the Nape-Common pairs of sensors should be as low as possible. The ALGO 5 device cannot begin (or continue) screening if the difference between these pairs is above 5 kOhms.

8 Attach acoustic transducers to earphones.

a Tear open the earphone pouch at the notch in the corner.

b **Before** removing the earphones from their liner, attach the colored transducers to the earphones. As the electrode / PCA cable and the coupler / ATA cable assemblies are placed on the baby, **ensure that the ATA cable does not directly overlap any of the electrodes**. Simply making sure these ATA cables are not touching an electrode can aid in reducing interference during the test.

Figure 25—Transducers attached to earphones



 © 2011 Natus Medical Incorporated

9 Apply earphones to baby.

a Remove each earphone from liner card and position over ear.

Blue transducer: **Left** ear **Red** transducer: **Right** ear

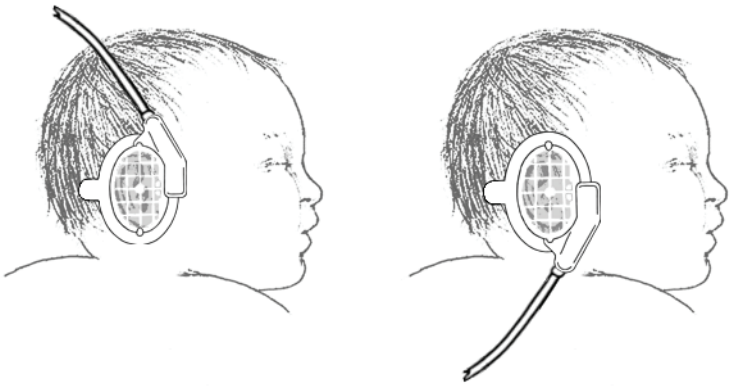
b Place the earphone so that the tab on the earphone is positioned behind the back of the ear.

c Position each earphone so the cable emerges either toward the top of the head or toward the baby's body.

d Roll the earphone from behind the ear to the front of the ear to attach to the baby.

The earphone must completely enclose the external ear and form a good seal all the way around. Avoid applying earphone to hair if possible. Ensure that colored transducer is in front of baby's ears.

Figure 26—Baby with earphones



The baby is now ready for screening.

⚠ **WARNING:** Any misuse of the earphones or the earphone cable (that is, any use other than what is described here) may result in screening at unknown and uncontrolled decibel levels.

⚠ **WARNING:** Never apply pressure to the ear canal or compress the tragus (the prominence in front of the external opening of the ear).

⚠ **WARNING:** Never insert the acoustic transducers directly into an ear.

Running the Screening Procedure

This section describes the following:

- Starting a test in Right/Left Simultaneous Screening method
- Observing the test parameters during screening
- Reviewing and printing results

Later in the section are descriptions of:

- How to pause a screening
- Right/Left Sequential Screening method
- Single-Ear Screening method

Right/Left Simultaneous Screening Method

These instructions apply to the Right/Left Simultaneous Screening method only. Instructions for using the Right/Left Sequential Method and Single Ear Screening method appear later in this section.

Once you prepare the baby and observe acceptable impedance readings, you may begin the screening.

1 Wait for the baby to sleep.

After applying sensors and placing earphones, wait until the baby is sleeping or in a relaxed state before beginning the screening.

Note: If you want to feed the baby to help it fall asleep, remove the clips from the sensors, but leave the sensors on the skin. It may also be easier to feed the baby without earphones in place; gently reposition earphones just before screening begins.

2 Select Begin Screening and observe display

From the Baby Preparation window, select **Continue (F1)**. You will be connected to the Screening window. Select **Begin Screening (F1)**. The screener presents click stimuli to both ears at once.

Messages and numbers appear and change periodically to reflect the screening in progress.

- The date and time of screening, along with the patient's medical record number and name appear at the top of the window.
- The word "Testing" indicates that clicks are being generated.
- **Impedance readings** allow you to watch for changing impedance between the sensors (refer to step 4). Impedance is also described in "Preparing the Baby for Screening" on page 39.
- **Ambient and myogenic interference indicator bars** allow you to evaluate conditions during the screening (refer to step 3). Interference indicator bars are updated regularly. While the screening is in progress, the bars will fill in green to show that some interference is present. The percentage of ambient and myogenic interference is displayed within the ambient and myogenic bars.
- The **screening application and screening method** are indicated in the top left area of the Screening window.
- A row of **command buttons** at the bottom of the window gives you access to several screening functions, including pause and help.

Note: It is not necessary to watch the display continuously during a screening. However, you should check the display occasionally in case the baby's condition or the environment unexpectedly changes.

 © 2011 Natus Medical Incorporated

3 Monitor interference occasionally.

The screener continuously monitors for two sources of interference:

- Ambient noise (room or baby)
- Myogenic activity (muscle or electrical interference).

An indicator bar is used to indicate the presence of interference.

The screener updates the display regularly. If there is any change in the environment, or the baby wakes up, the increased interference may slow the screening rate.

If an interference problem develops, pause the screening (see instructions immediately following this section). For complete information about troubleshooting interference problems, see "Ambient Interference" on page 63 and "Myogenic Interference" on page 65. Also select **Help (F12)** for troubleshooting tips.

IMPORTANT: Do not operate the screener in an environment where the screener continuously displays myogenic interference. Such interference may slow down or stop the screening and compromise the screener's performance or accuracy.

4 Monitor impedance occasionally.

Whenever an impedance reading rises to 12 kOhms or above, the screening pauses. Also, the appropriate sensor and border of the corresponding baby illustration flash red, and an accompanying message will appear indicating the problem sensors.

Screening cannot resume until you correct the high impedance condition.

Additionally, a reading of zero kOhm impedance may indicate a potential issue with the device. The ALGO 5 will warn you as to the occurrence of zero impedance.

IMPORTANT: If a zero impedance warning occurs while screening a baby, then the screen should be stopped and Natus Technical Service should be called.

5 Clip placement reversed.

If the nape (white) clip and vertex (black) clip are placed on the vertex and nape sensors respectively, you may see an error message:

CLIP PLACEMENT IS REVERSED

Select **OK** then correct the placement of the two sensor clips. You must rescreen the infant.

For troubleshooting, see “Impedance and Sensor Problems” on page 57. You can also select **HELP (F12)** on the Screening window for more troubleshooting tips.

IMPORTANT: If the nape, vertex or common sensor becomes detached, the impedance reading for the appropriate sensor will read ">99K" and the screening will pause. Also, the appropriate sensor on the corresponding baby illustration will flash red. Correct the sensor problem and select **RESUME (F1)** to resume screening.

6 Monitor for exceeding the typical time it takes to screen.

If the likelihood ratio continues to remain static or advance very slowly during a screening, the screener may display the following message:

YOUR SCREEN’S DURATION HAS EXCEEDED THE TYPICAL TIME IT TAKES TO SCREEN.

The screen will proceed while this message is displayed. Select **OK** to remove the message and continue screening.

7 Observe and record results.

Note: Record patient screening results according to your institution’s protocol. Record any additional information about the baby’s condition or screening procedure useful for your records.

With the Simultaneous Screening method, the screener displays the result for each ear as it is achieved. When screening of both ears is complete, the screener automatically prints the results. PASS and REFER conditions are described in “Pass/Refer Criteria” on page 9.

The screener also displays the following message:

SCREEN COMPLETED. SELECT OK TO CONTINUE.

Once you select **OK**, you will see the results displayed on the Screening window.

In addition to the PASS and REFER results, the screener also prints the values for % Myogenic Interference, Screen Duration, sweep count (SWEEP), user I.D., time of screen and institution I.D. on the printer label.

- **Screen Duration** is the total time the ALGO device was actively screening.
- **% Myogenic Interference** is the percentage of time during the test that the screener was not accumulating data due to myogenic interference.
    - **Time of Screen** is the time at which the user begins the screen (i.e., selects **Begin Screening**).

Note: Screen duration, percent of myogenic interference and time of screen values are printed on the result label.

 © 2011 Natus Medical Incorporated

Note: The myogenic interference value that is printed on the result label is an average of the percentage of myogenic interference that appears on the Screening window (in the form of an indicator bar). The value that appears on the Screening window reflects moment to moment changes in screening conditions while the screening is in progress.

- **Sweep Count (SWEEP)** is the number of "acceptable" sweeps accumulated by the screener.
- **User I.D.** is the name or initials of the individual performing the screen.
- **Institution I.D.** represents the name of your healthcare facility.

Note: If an ear does not pass, Natus Medical recommends a bilateral rescreening before hospital discharge, or according to your healthcare facility's protocol.

To print an additional copy of the results after the screening is completed, select **Print Letter (F5)** or **Print Label (F6)**.

Results for complete and partially complete screenings are stored in the screener's files and can be retrieved in the data management window. (For further information, see "Finding and Displaying Patient Records" on page 115.) If you interrupt the screening, results for the completed ear will be displayed in the data management window as PASS or REFER. Results for the unfinished ear will be displayed as N/A.

Note: If one ear finishes before the other, the screener displays PASS or REFER for the completed ear. The screener continues to display SCREENING for the remaining ear until the screen is complete.

Note: Screening Results Reporting will be based on selections made in ALGO 5 preferences.

⚠ **WARNING:** Do not screen any ear for more than 60 minutes in one 24-hour period. After 60 minutes, screening stops automatically, and the screener displays a message indicating that the time limit has been reached. You must return to the Main window. The screener prints any partial results at this time.

Pausing a Screening

You may pause the screening in order to:

- Intervene if high ambient or myopgenic levels are slowing down the screening
- Get a baby back to sleep
- Use on-line Help (see "Using Online Help" on page 55).

When you pause a screening, the screener retains all data collected up to that point. After intervening (correcting high impedance, calming the baby, etc.), you can resume screening without starting from the beginning.

To pause a screening in progress:

1 **Select Pause Screening (F1).**

The screener stops and displays "Paused" instead of "Testing".

Note: If the screener has reached a result condition for one ear before the other ear is completed, the display will indicate PASS or REFER for the ear completed and PAUSE for the ear still being screened.

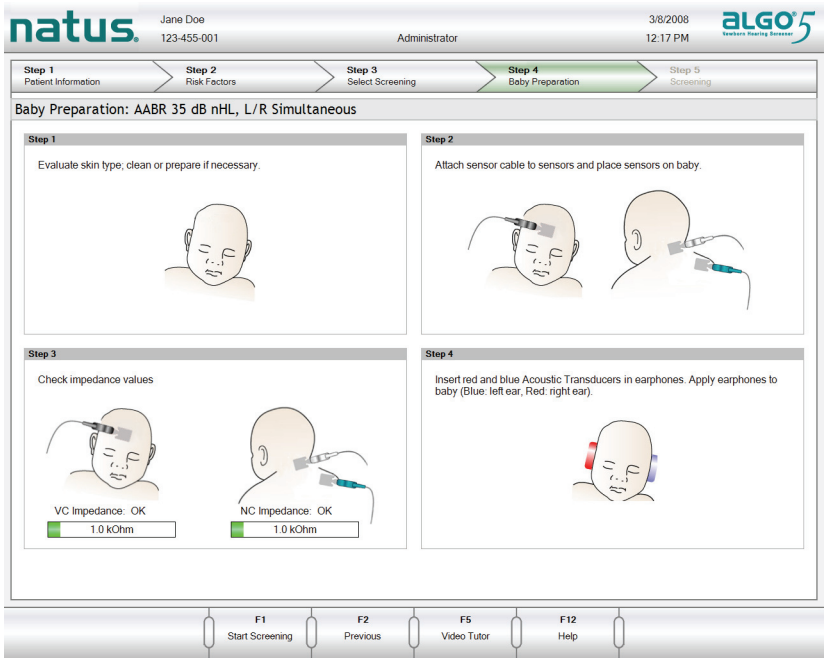
2 Resume screening after intervention.

When you are ready to resume screening, select **Resume Screening (F1)**.

Right/Left Sequential Screening Method

If a baby is easily aroused by the simultaneous presentation of clicks, you may choose to screen the ears sequentially. After entering patient information, proceed to the Screening Method Selection. Select the R/L Sequential method and then select Continue (F1). The Baby Preparation window appears.

Figure 27—Baby Preparation window



Proceed to prep the baby and check impedance readings.

IMPORTANT: Be sure to place both earphones on the baby before beginning, as the screener switches automatically from the right to the left ear without interruption.

When you begin screening, the test runs in the same way as in the Simultaneous Screening method, except that the acoustic transducers present clicks to one ear at a time.

 © 2011 Natus Medical Incorporated

After the right ear is completed, the display indicates PASS or REFER for the right ear, and “Testing” for the left ear. The screener prints out the results when both ears are completed.

Single-Ear Screening Method

Use this method to screen one ear at a time, or to rescreen an ear that did not pass. When rescreening an ear, select **Rescreen Same Baby (F5)** from the Screening window. You will return to the Screening Method Selection window. You do not have to re-enter patient information. Select Right Only or Left Only. Once you have made the appropriate selection, select **Continue (F1)** to move on to the Baby Preparation window.

Prepare the baby and check impedance. After the baby is asleep and you start the screening, the acoustic transducer presents clicks to the ear being screened.

IMPORTANT: If you screen only one ear, be sure to use the correct acoustic transducer with the correct ear. Use RED for the right ear or BLUE for the left ear. Do not place the unused transducer near the baby’s head or on the screener. It is good practice to store the unused transducer on the Acoustic ATA Check on the ALGO Check kit.

Note: The Single-Ear Method will not appear as a choice in the Screening Method Selection window unless specifically requested by your system administrator in the preferences set at the time of installation.

Cleanup

After screening ends, complete the following procedure.

1 **Remove the clips.**

Remove each clip from its sensor by pinching the open end of the clip.

2 **Clean sensor cable.**

Clean the sensor cable according to your health facility’s protocol on cleaning equipment that has come into contact with patients.

IMPORTANT: Refer to your health facility’s protocol for guidelines on how frequently to clean equipment that comes into contact with the patient.

3 **Store sensor cable.**

Place the preamplifier and sensor cable in the storage drawer on the cart, on the cable hanger assemply at the back of the cart, or on the cable tray.

CAUTION: Do not allow cables to dangle near the cart wheels or floor. They can be easily damaged.

4 **Remove earphones and acoustic transducers together from the baby.**

5 Remove acoustic transducers from earphones.

CAUTION: Do not tap transducer tips on any surface to dislodge internal debris. Do not insert any implement inside the transducer tips.

CAUTION: Do not allow liquids to enter the holes on the transducer tips. Liquid may irreparably damage the internal components of the ATA cable.

6 Clean earphone cable.

Clean the earphone cable according to your health facility's protocol on cleaning equipment that has come into contact with patients.

7 Store earphone cable.

Place the earphone cable in the cart drawer.

8 Remove sensors.

Remove the sensors from the skin. They generally come off easily, but sometimes the sensors require special attention.

If a sensor seems stuck, support the underlying skin with your fingers and gently lift the edge of the sensor. Use water on gauze to saturate and soften the hydrogel along the sensor edge. Gently work the sensor loose.

Figure 28—Using Moistened Gauze to Ease Sensor Removal

⚠ **WARNING:** Do not leave sensors on a baby for prolonged periods. If the baby perspires under a sensor that has not been removed, irritation may develop.

 © 2011 Natus Medical Incorporated

9 **Clean skin with water.**

Wash each sensor site with water and gauze to remove any residue left by the sensors or prepping materials.

10 **Dispose of single-use patient items properly.**

IMPORTANT: Jelly Tab sensors and Flexicoupler earphones are for single-patient use only. Discard properly after each screening.

If you are screening another baby without moving the device, choose **Screen Next Baby (F5)**.

If you choose to rescreen the current baby again immediately, choose **Re-Screen Baby (F1)**

Proper Shutdown Procedures

CAUTION: **Failure to shut down properly may lead to problems with the stability of the database containing patient data.** Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures.

If you are moving the device or are done for the day, choose **Main Window (F10)** and then choose **Exit (F10).**

The menu choices will now be:

Hibernate (F1)

Power Off (F2)

Log Off (F3)

If you are moving the device to another area to continue screening, choose **Hibernate (F1)**.

The computer will begin hibernating and this process can take a few minutes. No visual progress will be obvious during this time. Allow the device to finish the action as evidenced by the power light on the front of the Panel PC completely turning off.

At this point once the computer has hibernated, you may unplug and move the device.

If you are turning the device off at the end of the screening, OR in order to:

- troubleshoot,
- cycle the power,
- connect or disconnect any accessory, or
- clean any part of the device

choose **Power Off (F2)** and confirm your choice.

⚠ **WARNING:** Do not turn screener off while baby is still connected.

The computer will begin shutting off and this process can take a few minutes. No visual progress will be obvious during this time. Allow the device to finish the action as evidenced by the power light turning off.

At this point once the computer has shut down, switch off the Main Power switch at the bottom of the column.

The power cord may now be unplugged and draped over the top of the column or wrapped around the cleat on the bottom of the column.

Cable Storage

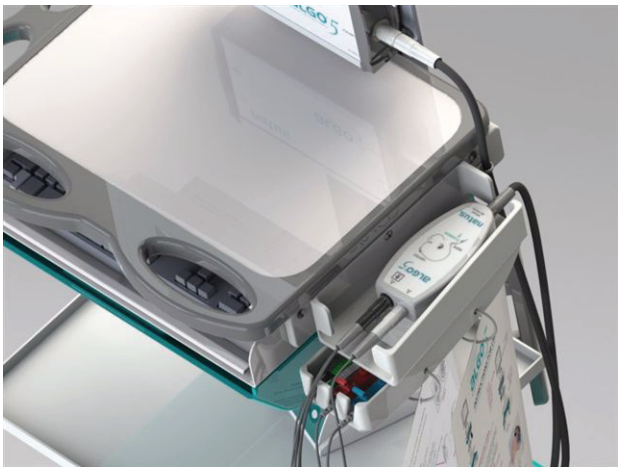
Natus advises you to store the cable ends (those that contact the supplies) in a manner so as to provide them protection from accidental impact.

a) They can be stored on the back of the device **by hanging the ends on the forked metal bracket**.

b) The ends can also be **brought around to the front of the device and placed into the drawer**. (Care should be taken to ensure that the cables are not caught in the drawer runners if this method is used.)

Natus is also providing an additional storage option of an attachable tray for the storage of the PreAmp body and the PCA and ATA cables.

Figure 29—Attachable tray for storing PreAmp body and PCA and ATA cables



This tray can be attached to the side of your ALGO 5 cart and will serve as an additional option for protection and storage of the sensitive components. See the installation instructions included with the tray.

 © 2011 Natus Medical Incorporated

Troubleshooting

This section discusses typical problems you may encounter during screening, some possible causes, and suggestions for resolving them. It covers the following topics:

- Using On-Line Help: see “Using Online Help” on page 55
- Impedance and sensor problems: “Impedance and Sensor Problems” on page 57
- Prepping techniques: see “Prepping Techniques” on page 60
- Ambient interference: see “Ambient Interference” on page 63
- Myogenic interference: “Myogenic Interference” on page 65
- Understanding referrals: see “Understanding a “REFER” result” on page 67
- Error messages and system failure: see “Error Messages and System Failure” on page 69
- How to run an equipment check: see “Equipment Check” on page 70

When you encounter a problem, remember that the screening process has three variables:

1) Screening Device 2) Environment 3) Baby

All problems are caused by one or more of these variables. Whenever you have a problem during screening, always begin by looking first at the screener, then the environment, and then the baby. This is the most direct course to understanding how to screen efficiently.

If difficulties continue after following troubleshooting suggestions, contact Natus Medical Technical Service or your authorized service representative.

For service information, see "Service and Maintenance Procedures."

Using Online Help

You can get help at any phase of the screening process by selecting **Help (F12)**. You will be connected to a Help display.

There are several topics available to you; they are listed on the left-hand side of the window. Use the up and down arrow keys to highlight your selection. Information appears to the right of the topics.

Help Topics:

- **Requesting Service** displays the phone number and address for Natus Medical Technical Support and Customer Service.

- **Tutorial** provides you with a movie that presents information about baby preparation, troubleshooting sensor impedance, myogenic or ambient interference. This movie lasts approximately seven minutes. To play, pause or stop the tutorial, use the pointing device to select the appropriate command. Using the pointing device, select **Previous Window**, located at the bottom of the Tutorial display to return to the Help topics.

Using Help

To use on-line help:

1 **Select Help (F12) located at the bottom of all screener windows. Select the help topic.**

2 **Read or view the information.**

3 **Select Previous Window (F2) to return to the previous display.**

To resume screening after using on-line help:

1 **Select Previous Window (F2).**

From the Help display, select **Previous Window (F2)**. The screener returns to the Screening window.

2 **Select Resume Screening (F1).**

From the Screening window, select **Resume Screening (F1)**. The screener begins screening again.

Note: To stop a screening in progress and return to the Main window, select **Stop Screening (F3)**. The screener stops the screening in progress; the result for a completed ear will be stored in audble records as PASS or REFER. The results for an unfinished ear will be stored in audble records as N/A.

Artifact Rejection Systems

In order to effectively troubleshoot the screener, it is useful to understand its two artifact rejection systems. These systems protect the data being collected from contaminating interference.

To ensure that the baby's ABR is only made up of responses to the screener's clicks, small microphones in the acoustic transducers listen between clicks for noise under the earphones. If a noise is too loud (or too soon after the screener click), the screener activates the ambient noise rejection system. The screener stops collecting data until the noise stops.

The myogenic interference rejection system assures that interfering electrical (non-EEG) signals are filtered from the responses being collected from the baby. The screener monitors myogenic (muscle movement) and electrical interference; it suppresses contaminated sweeps.

Expect a small amount of interference during most screenings, especially at the beginning of a screen before the baby is completely settled and quiet. It is only when interference is constant, and the screening is slowing down or stopping, that you should intervene and try to correct the situation.

 © 2011 Natus Medical Incorporated

Impedance and Sensor Problems

If impedance readings at the sensor sites are greater than 12 kOhms during baby preparation, the screener displays an error message and you cannot start testing. Examples of impedance problem errors include:

IMPEDANCE BETWEEN NAPE AND COMMON IS TOO HIGH. PLEASE CHECK ELECTRODES.

ELECTRODE IMPEDANCE IS TOO HIGH. PLEASE CHECK ELECTRODES.

IMPEDANCE BETWEEN COMMON AND VERTEX IS TOO HIGH. PLEASE CHECK ELECTRODES.

If impedance readings display 12 kOhms or greater during screening, the ALGO screener stops and displays a “Check Sensor” message. Screening cannot continue until the readings are less than 12 kOhms.

For quick access to troubleshooting instructions, select the “Jelly Tab Sensors” help topic from the Help Menu.

For a description of the reprep method cited on this display, see “Reprep Method” on page 61. Additional instructions for troubleshooting impedance problems are provided on the following pages.

Note: The ALGO 5 screener will warn of high mismatched impedance between the vertex-common and nape-common pairs. The difference between electrode pairs should be as low as possible. So while an impedance reading shown on the Baby Preparation screen may be low enough to proceed with screening previously, a condition where the two readings are sufficiently different will cause the ALGO 5 device to warn you of this condition and may pause the test. Follow the reprepping techniques outlined in the ALGO 5 User Manual for this condition, the same as you previously did for individual electrode impedance problems.

Check Screener

If a reading is “99 kOhms,” suspect an equipment problem.

IMPORTANT: If impedance readings remain “99 kOhms” after careful prepping, perform an impedance check to rule out the chance that your preamplifier box or sensor cable is damaged. Do not reprep until after you perform this check. (See “Equipment Check” on page 70 for instructions on performing this check.)

Are sensors correctly placed and attached?

- Be sure sensors are placed correctly on the head, neck, and shoulder.

  Black clip to **Vertex** sensor (center forehead, as high as possible)
  White clip to **Nape** sensor (center and back of neck)
  Green clip to **Common** sensor (shoulder)

- Be sure no sensor has been pulled off the skin by the baby's movements.

Is sensor cable correctly connected?

- Be sure each clip is connected to the correct sensor. Be sure no clip has come loose or been disconnected by the baby's movements.

  If a clip is not attached to the correct sensor, you may see the following message:

  NAPE AND VERTEX SENSORS ARE REVERSED. CORRECT CLIP PLACEMENT AND RESCREEN.

- Be sure the sensor cable is plugged securely into the preamplifier box.

Is preamplifier cable properly connected?

- Be sure the preamplifier cable is securely plugged into the correct port on the screener. Ensure that the alignment arrows on the cable and the DSP align. Do not force the connection. Do not twist connection. You may see the following message:

  PREAMP CABLE NOT CONNECTED.
  1. ENSURE THAT THE PREAMP CABLE IS PROPERLY CONNECTED.
  2. IF THE ERROR IS REPEATED, CONTACT NATUS TECHNICAL SERVICE.

CAUTION: Before...

cycling the device power via the power switch on the column, or
unplugging the device, or
connecting or disconnecting cables, or
cleaning the device

...power off the device via the computer menu selections available. **Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown.**

The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate." Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to "Proper Shutdown Procedures" on page 53.

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to "Proper Shutdown Procedures" on page 53.

 © 2011 Natus Medical Incorporated

Does sensor or preamplifier cable appear damaged?

- Examine sensor and preamplifier cables for obvious damage or exposed wires. Be sure connector pins are not bent.

IMPORTANT: Do not use a cable that is damaged or has exposed wires or electrical connections. Broken cables may cause excessive interference, screening delays, and inaccurate results.

Are sensors adhering properly?

- Remove oil and dry skin cells by prepping or washing the skin.
- Remove all Nu Prep gel with damp gauze before replacing sensor.
- Handle sensor only by the tab or by the edge. Replace on plastic liner when reprepping. Do not place a sensor on the back of your hand, or a piece of cloth (such as a gown or blanket) while reprepping. The sensor will pick up dry skin and lint.
- Use fresh sensors if necessary.

Are sensors dried out or otherwise damaged?

IMPORTANT: Do not use expired product.

- If the sensors appear discolored or hard and not sticky when removed from their foil pouch, contact Natus Medical Technical Service or your authorized service representative.

IMPORTANT: Do not use damaged sensors.

Check Environment

This area of possible solutions is not applicable for impedance problems.

Check Baby

If one or both impedance readings are between 12 kOhms and 99 kOhms, then the sensor sites may need further preparation. “Prepping Techniques” on page 60 gives detailed instructions for preparing the sensor sites.

Before prepping, consider carefully the baby’s condition:

Is baby’s skin especially oily?

- Wash skin with soap, water, and a washcloth prior to prepping.
- Use a liquid prep as explained in the Reprep Method (following this section), and be careful not to abrade the skin.

Is baby’s skin especially dry?

Some babies have very flaky skin and require more careful prepping.

- Reprep with Nu Prep gel as explained in the Reprep Method (following this section).
- Apply a small drop of normal saline solution to the sensor surface or directly onto the skin.

- If alcohol was used to remove oils or lotion, be sure the skin is then gently cleaned with water to remove dry skin, then rehydrate the surface skin before placing sensor.

Was prepping sufficient and done correctly?

- Remember the entire adhesive surface of the sensor is conductive. Prep an area slightly larger than the sensor.
- Place the sensor exactly over the site you prepped.
- Follow the "Reprep Method" on page 61, and be careful not to abrade the skin.

Prepping Techniques

Prepping reduces electrical impedance across the baby's skin, which allows for better electrical conductivity. This is especially important because the screener searches for electrical signals that are very small compared to other electrical activity in the baby's brain and body.

Conductivity is enhanced by moisture, for example, the fluid in skin cells or saline solution. Conductivity is impeded by dry skin, surface oil, or the drying effect of alcohol.

Different types of skin require different types of prepping.

- Skin with oil or lotion responds well to cleaning with mild soap and water followed by prepping with Nu Prep gel.
- Dry skin often responds best to prepping with saline or Nu Prep gel followed by a drop of saline under each sensor.

Careful prepping is required for infants with oily skin or body hair at the sensor sites. These characteristics are associated with high impedance readings.

IMPORTANT: These techniques are recommended for prepping a full term, healthy newborn. Please read and understand the following guidelines and tips before prepping any infant.

- **Premature infants.** Be sure the infant is at least 34 weeks corrected gestational age. Use extra care when prepping any baby born prematurely, who may still have fragile skin.
- **Compromised skin.** Never prep, or apply sensors to, damaged or compromised tissue. If irritation develops, stop prepping and wait a few minutes. Make sure any redness is gone before trying again. Use a new area of skin if possible.
- **Consult your nursery's procedures** to determine which prepping materials are permitted (for example, soap, alcohol, etc.). Remember that some babies may be sensitive to any product applied to the skin. If irritation develops, discontinue use and seek appropriate medical care.
- **Prep with friction, not force.** Do not break the skin. Overprepping can lead to adverse skin reactions.
- **Do not use excessive pressure** when prepping near an infant's fontanel. Do not cut an infant's hair, or shave the head.

 © 2011 Natus Medical Incorporated

Reprep Method

Use this prepping procedure if impedance readings are too high or if the impedance mismatch is too great.

1 Decide which site to prep first.

- If both Nape Impedance and Vertex Impedance readings are 12 kOhms or higher, prep Common site first.
- If only Nape Impedance is 12 kOhms or higher, prep Nape site first.
- If only Vertex Impedance is 12 kOhms or higher, prep Vertex site first.

Note: If a reading is “99 kOhms,” check the sensor and preamplifier cables to be sure they are functioning properly. Be sure sensors and clips are secure. (See “Impedance Check” on page 73.)

2 Remove sensor.

Gently lift the tab of the sensor while supporting underlying skin with your fingers. Handle sensor only by its edges and place it on its plastic card. Do not allow the conductive side of the sensor to touch your skin or any cloth surface.

⚠ **WARNING:** If you feel resistance, moisten a gauze sponge and work it under the edges of the sensor to loosen the hydrogel seal.

3 Wash sensor site with soap and water.

Use a gauze sponge and mild soap to gently clean the sensor site. Be sure to remove any traces of soap.

Note: Since the entire surface of the sensor is conductive, clean and prep an area slightly larger than the sensor.

4 Prepare site with Nu Prep gel.

a Apply gel. Put a small amount of NuPrep gel (about the size of a pencil eraser) on the corner of a gauze sponge. Hold skin taut and scrub the site gently. Be sure you are moving the gauze over the skin, and not just moving the skin with the gauze. Prepare an area slightly larger than the size of the sensor.

b Remove gel. Use a damp cloth or gauze to remove excess gel. Be sure the skin is not dripping wet before replacing sensor. Pat lightly with dry gauze as needed. (Residual gel can increase impedance. Also, some moisture is good for conductance, but excess water can cause sensor to slip off.)

IMPORTANT: Refer to the skin prep package insert that accompanies the NuPrep gel for complete instructions, including all warnings, cautions, and specifications.

5 Replace sensor and check impedance readings.

- If readings are less than 12 kOhms, proceed with the screening.

- If readings range from 12 kOhms to 20 kOhms, leave sensors on skin. If readings are too high after the sensors have settled for 2 to 3 minutes, place a small drop of saline on each site and reapply sensor. The saline may add enough moisture to adequately decrease a marginal impedance reading. If you use too much saline, you will have to wait for it to dry, or the sensor might slip off. The readings may drop to acceptable levels.
- If readings remain 12 kOhms or greater, further prepping is needed (step 6).

6 Prep remaining sites and recheck readings.

As in steps 2-4, remove the other two sensors, wash sites with soap and water, and then prep with NuPrep gel. Replace sensors and recheck readings.

- If readings are acceptable, proceed with the screening.
- If readings are still too high, further prepping is needed.

7 Apply a small drop of saline.

8 Remove and discard sensors (Reprep Rule).

If readings are still too high, remove all three sensors as in step 2 and discard. Use a fresh set of sensors for subsequent checks.

> **Note:** Use a new sensor whenever a site has been prepped **twice**; the hydrogel may no longer be adequately conductive. Natus Medical suggests thinking of this as the **Reprep Rule**: "If you have prepped twice, try a fresh sensor." (Note that when you detach the sensor, some surface skin debris will also be removed, which can improve conductivity.)

9 Prep sites again, place new sensors, and recheck readings.

At this point, reprep the sites with NuPrep gel (step 4). Remember that every baby is different. Also, with experience, prepping becomes easier.

⚠ **WARNING:** If impedance readings are still too high after reprepping, wait a few minutes before resuming.

When to use alcohol:

In ***exceptional*** cases (for example, a baby who has oil or lotion on the skin, and for whom washing with soap and water has not cleaned the skin), try an alcohol swab. The alcohol removes oil, but it also dries the skin. Allow alcohol to dry thoroughly and follow with a wet wash with gauze. Then prep with NuPrep gel before placing the sensor.

⚠ **WARNING:** Do not use soap or alcohol if your nursery prohibits its use on newborn skin. Do not prep skin that is still wet with alcohol. Since alcohol dries the skin, sensors will not effectively attach unless skin has been prepped with a wet wash and/or NuPrep gel.

 © 2011 Natus Medical Incorporated

Ambient Interference

When the screener detects room noise, the **Ambient Noise** bar fills with color. The percentage of ambient noise is displayed within the ambient bar.

In the case of excessive ambient noise (sustained noise greater than 30%) the following events occur:

- The screening will slow down or it may completely stop.
- A "Check Ambient Noise" message will display above the ambient bar.
- When more than 90% of the indicator bar is filled, the bar color becomes red and a red indication will flash on the earphone illustration.

Select **Help (F12)** at the bottom of the Screening window. Select either the tutorial or the "Ambient Interference" help topic for troubleshooting tips. Additional troubleshooting instructions are given in the following sections.

Check Screener

Is the earphone cable connected to the screener?

Be sure the earphone (ATA) cable is properly attached to the PreAmp cable and ensure the PreAmp cable is properly attached to the DSP Box.

CAUTION: Before...

cycling the device power via the power switch on the column, or
unplugging the device, or
connecting or disconnecting cables, or
cleaning the device

...power off the device via the computer menu selections available. **Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown.**

The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate." Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to "Proper Shutdown Procedures" on page 53.

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to "Proper Shutdown Procedures" on page 53.

Are you using the earphone cable correctly?

When screening using a Single-Ear method, be sure the method matches the ear you are testing. The method name appears at the top left area of the display,

either "Right ear only" or "Left ear only." Use the **red** transducer for the **right** ear and the **blue** transducer for the **left** ear.

IMPORTANT: If you screen only one ear, be sure to use the correct acoustic transducer with the correct ear. Use **RED** for the **right** ear or **BLUE** for the **left** ear. Do not place the unused transducer near the baby's head or on the screener. It is good practice to store the unused transducer on the Acoustic ATA Check on the ALGO Check kit.

Is the earphone cable damaged?

Carefully inspect the connector, wires, and transducers themselves. If there are any loose or exposed wires or connections, do not use the damaged component and contact Natus Medical Technical Service or your authorized service representative.

IMPORTANT: Do not use a cable that is damaged or has exposed wires or electrical connections. Broken cables may cause excessive interference, screening delays, and inaccurate results.

Are earphones properly placed?

Be sure the earphones are positioned so the earphone cable emerges toward the top of the baby's head. See "Preparing the Baby for Screening" on page 39 for proper earphone placement.

Are earphones staying on the baby?

- Be sure you are not reusing earphones.
- Be sure the earphones are not coming off, and that proper placement is maintained. This is very important; the earphones block out ambient noise.

⚠ **WARNING:** Do not use anything to bind earphones to a baby's head in any way that compresses or closes the ear canal.

Check Environment

Is there too much noise in the area?

- Reduce conversation and other loud noises in the immediate vicinity.
- If there are loud fans, alarms, or other equipment in the area that could trigger the ambient rejection system, then you should wait to screen until later or move to another location.

Check Baby

Is the baby crying?

- Pause the screening until the baby quiets down.

 © 2011 Natus Medical Incorporated

Myogenic Interference

When the screener detects muscular or electrical interference, the **Myogenic Noise** bar fills in with color. The percentage of myogenic interference is displayed within the myogenic bar.

In the case of excessive myogenic interference (greater than 50%) the following events occur:

- The screen will slow down or it may completely stop.
- A "Check Myogenic Noise" message will display above the myogenic bar.

When more than 90% of the indicator bar is filled, the bar color becomes red.

Select **Resume Screening (F1)** to continue with the screen, or select **Stop Screening (F2)** to stop the screen.

Select **Help (F12)** at the bottom of the Screening window. Select either the tutorial or the "Myogenic Interference" help topic for troubleshooting tips.

It is important to remember that myogenic interference can originate from one of the three system variables: the screening device, the environment, or the baby. Follow the steps listed below, in the order they are given, to eliminate each variable from the system and determine the source of your problem.

Check Screener

Are you using the sensor cable correctly?

- Attach the correct cable to the correct sensor site.

  Black clip to **Vertex** sensor (center forehead, as high as possible)
  White clip to **Nape** sensor (center and back of neck)
  Green clip to **Common** sensor (shoulder)
- Be sure the common sensor is not too close to the nape sensor.
- Be sure the preamplifier box is not too close to the screener's display.

Is the sensor cable damaged?

Carefully inspect the connections, preamplifier box, wires, and clips. Do not use any equipment with loose or exposed wires or connections. Contact Natus Medical Technical Service, or your authorized service representative.

IMPORTANT: Do not use a cable that is damaged or has exposed wires or electrical connections. Broken cables may cause excessive interference, screening delays, and inaccurate results.

Perform an Impedance Check

See "Equipment Check" on page 70 for directions on how to perform an Impedance Check. This check verifies that the sensor and preamplifier cables are working properly and are not the source of your myogenic interference.

Check Environment

IMPORTANT: Do not operate the screener in an environment where the screener continuously displays myogenic interference. Such interference may slow down or stop the screening and compromise the screener's performance or accuracy.

IMPORTANT: Do not operate the screener if cardiac monitors or incubator fans in the near vicinity (or other equipment required for monitoring a very sick infant) are causing interference.

Perform an Artifact Check

See "Equipment Check" on page 70 for directions on how to perform an Artifact Check. This check identifies the source of myogenic interference.

> **Note:** This is a valuable check. With it you can establish whether the baby is the source of the interference. If the screener passes the Artifact Check, you can be sure that the myogenic interference is coming from the baby, no matter how it may appear.

During screening, the following dialog box may appear:

> **EXCESSIVE NON-PHYSIOLOGIC NOISE IS PRESENT. ENSURE THAT NO OTHER ELECTRICAL EQUIPMENT IS IN CLOSE PROXIMITY TO THE SCREENING AREA.**

Try to identify this artifact source and move the screener and the baby away. Select **Resume Screening** to continue the current screen, or **Stop Screening** to stop the current screen.

> **Note:** Use **Stop Screening** if the screener must be powered off and unplugged to move away from artifact source.

Is source of artifact near you in the room?

If the Artifact Check points to the environment, turn off the screener by following the specific instructions for proper shutdown. (See "Proper Shutdown Procedures" on page 53.) Move the screener to another location and perform the Artifact Check in the new location. Then, move the baby to the new location for screening.

- Check for monitors, infusion devices, pumps, and phototherapy lights in the immediate vicinity.
- Is the screener next to a large metal cart or sink, or a bank of power outlets? Is it near large instruments such as x-ray equipment?

⚠ **WARNING:** Do not turn off any equipment suspected of causing interference unless under the direct supervision of a physician or appropriate medical practitioner.

 © 2011 Natus Medical Incorporated

Check Baby

Note: Consult your healthcare facility's protocol for instructions on handling babies in the nursery.

Is the baby too alert?

- Prep the skin and verify impedance readings. Optimal screening time is following a recent feeding or when the baby is asleep.
- Check the baby for a dirty diaper.
- Swaddle or rock the baby, or have a parent hold the baby. It is okay to screen while the baby is nursing.
- Reduce lighting or otherwise reduce stimulation.

Is the baby sucking a pacifier too much?

- Wait until sucking slows or remove the pacifier before screening.
- If the common sensor is on the cheek, move it to the shoulder.

Is the baby clenching its jaw?

- Massage cheek to relax jaw, or open mouth gently and close again to release tension.
- If the common sensor is on the cheek, move it to the shoulder.

Is the baby the right age for screening?

- Babies should be at least 34 weeks (gestational age) and not older than six months.
- Babies between three and six months of age may be more active, or have difficulty falling asleep, especially in an outpatient setting. Assure plenty of time for screening, and enlist a parent's help in quieting an older infant.

Does the baby's medical record chart indicate compromising medical conditions?

- Wait until medical problems are resolved whenever possible.
- If a baby is receiving or withdrawing from drugs or medications that affect the central nervous system (for example, drugs of abuse and bronchodilators), wait and screen at a later date whenever possible.
- Myogenic interference is more likely in some babies with a history of seizures.
- Do not screen right after a heel-stick, circumcision, or other painful procedure. Do not screen during medication infusions.
- In the NICU, screen as close to patient discharge as possible. In the well-baby nursery, allow time to rescreen before discharge if necessary.

Understanding a "REFER" result

The most obvious reason for a baby generating a "REFER" result is if he or she has a hearing impairment. This can only be fully diagnosed with a complete audiological workup.

The screener's decision to award a PASS or REFER depends on the probability that a response is present. If the ALGO screener is unable to establish with

>99% statistical confidence that an ABR signal is present after maximum number of sweeps, the screener will grant a “REFER” result. This means that the ALGO screener could not determine a response with sufficient statistical confidence.

There are a few things that can make the screening more difficult, and increase the chances of obtaining a "REFER" result in the presence of normal hearing.

- Sound is not getting from the screener to the baby the acoustic connection between the screener and baby is inadequate or interrupted.
- The baby’s response is not getting back to the screener -- the baby is in a non-ideal state during screening or equipment has failed.
- Interference is preventing the screener from detecting the baby’s signal -- there is sufficient interference (electrical noise) to mask the ABR.

When looking for ways to understand a "REFER" result, it is helpful to think once again in terms of the three system variables: the screening device, the environment, and the baby.

Check Screener

Is the earphone cable being used correctly?

- Check that the earphone cable is plugged into the cable panel correctly and securely.
- Check that the tips of the transducers are not plugged, blocked, or touching the baby’s ears. Also be sure the transducer tips are not lodged behind the ear.

Is the screener functioning properly?

- Listen at the ends of the transducers. You should be able to hear the click sounds during screening.
- Inspect the screener. Do the transducers appear damaged? Inspect the transducers and cables for any signs of damage. Do not use damaged cables.
- Perform an Acoustic Check and an Artifact Check. (See “Equipment Check” on page 70)
- Be sure the earphone cable (ATA) has been calibrated within the last year.

Check Environment

Excessive interference during a screen (from a noisy room or nearby electrical sources) may reduce the signal-to-noise ratio to such an extent that the screener cannot detect the signal. See “Ambient Interference” on page 63 and “Myogenic Interference” on page 65 for information about reducing interference.

 © 2011 Natus Medical Incorporated

Check Baby

Note: Screening babies who do not meet the criteria listed in section "Selecting a Baby" on page 32 may result in a higher than average incidence of referrals. The screener is not designed to screen infants who have known neurological abnormalities, obviously malformed ears, or who are acutely ill.

Is the baby too active to screen?

- A baby may be awake and moving around, or asleep but sucking excessively. If there is a great deal of interference from an active baby, the resulting signal-to-noise ratio may be too small for the screener to extract a signal.
- Rescreen when the baby is healthier, older, or sleeping quietly (see "Ambient Interference" on page 63 and "Myogenic Interference" on page 65 for information for information on troubleshooting screens with excess interference).

Is the baby's ear canal compressed?

Newborn ear canals are flexible. Sometimes external pressure to the ear will compress the ear canal and temporarily block sound.

- If the baby is lying on the ear that referred, turn the baby's head so that ear is "up," adjust the earphone, and rescreen.
- If you suspect a closed ear canal, remove the earphone. Pull gently on the skin in front of the ear canal (toward the face) to open the ear canal.
- Be sure to place the earphones correctly, rolling each earphone from the back to the front of the ear. Do not push too hard over the front edge of the earphone.

Refer the Baby for Follow-up

If upon rescreening, the baby still does not pass, refer the baby for diagnostic follow-up according to your institution's protocol.

Error Messages and System Failure

This section describes possible error messages that may appear when the screener is first turned on, or during screening.

Printer Error

The Printer Error message appears if the printer is not turned on, is disconnected, is out of labels, or there is a label jam or misfeed.

Verify that the printer is turned on, is properly connected, and that there are labels loaded. If you suspect a jammed or misfed label, see "Correcting a Printer Jam" on page 82. After correcting the problem, select RETRY to resume printing.

System Error

An error message may appear immediately after you turn on the screener or during screening in the event of hardware or communications failure or as a result of electrical interference.

Serial communication between the device and the host computer may be lost as a result of electrical interference. When communication is lost, the test can be re-started after the interference has ended.

To reset the system, turn off the screener by following the specific instructions for proper shutdown (see "Proper Shutdown Procedures" on page 53), ensure that the earphone and Preamp cables are properly connected, then turn the screener back on. This error message and subsequent recovery process was designed to prevent a false test of a patient from occurring in the event of a hardware or communications failure.

⚠ **WARNING:** Do not turn the screener on or off while the baby is connected.

Time Limit

Exceeding the Typical Screen Duration: This message occurs when the typical screen duration has been exceeded. The screener displays the following message:

YOUR SCREEN'S DURATION HAS EXCEEDED THE TYPICAL TIME IT TAKES TO SCREEN.

The screen will proceed while this message is displayed. Select **OK** to remove the message and continue screening.

Equipment Check

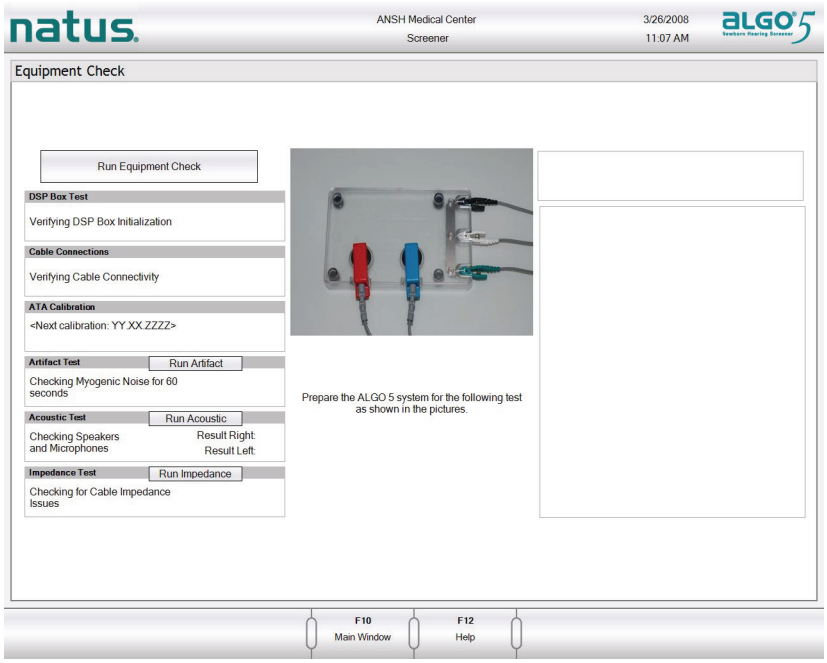
If a problem is suspected with the ALGO 5 hearing screener, then select **Equipment Check (F5)**. This function may also be requested by Natus Medical Technical Service during a service call.

1. **For an Equipment Check, a Natus Medical ALGO Check Kit is required (REF 040527).**
2. **Remove the Natus Medical ALGO Check Kit from the cart drawer and place it on a flat surface.**
3. **Select Equipment Check (F5) from the Main window.**

   The following window will appear:

 © 2011 Natus Medical Incorporated

Figure 30—Equipment Check window



The Equipment Check window displays photos of the correct attachment of the cables to the ALGO Check Kit. As you complete the task at each step, carefully examine the message at the top of the display to verify that the screener is operating properly.

4 **Select Run Equipment Check to check all components of the ALGO 5 system at a single time.**

5 **Set up the ALGO Check Kit with the ends of the ATA transducers in the black rubber gaskets and the PCA clips on the metal clips.**

The Equipment Check will then check the DSP box, ATA and PreAmp cable connections, ATA calibration, artifact check, acoustic check, and impedance test in order, without need for user interaction.

Note: This artifact test takes 60 seconds to complete. No user interaction is required during this time. This portion of the Equipment Check will yield a result based on the analysis during this time.

6 **Should any test fail, verify connections, check that cables are not twisted or wrapped around themselves or other electronic equipment, or move the screener to a different environment in cases of interference. Then select Retry Test.**

Note: Artifact Test, Acoustic Test, and Impedance Test can be run individually. See individual sections for the instructions for these tests.

7 **If a test continues to fail, please call Natus Medical Technical Service or your authorized service center.**

During an Equipment Check, the screener performs three tests to verify that it is operating correctly, or identify the source of a problem if there is one.

- **Artifact Check**: Indicates whether myogenic interference is coming from the baby, the environment, or the screener.
- **Acoustic Check**: Indicates whether the earphone cable is performing appropriately, the speakers are generating clicks, and the microphones are "listening." This is not an indication of calibration.
- **Impedance Check** (PCA Clip Check): Indicates whether the sensor or preamplifier cable is damaged, differentiating a broken cable from other problems. Note that the device may warn you if it detects zero impedance. When using the Check Kit, this may be expected and the Equipment Check can be continued. Do not, however, screen an infant when the device warns of zero impedance, because this may indicate an issue with the device. Contact Natus Technical Service.

In addition, during an Equipment Check the screener performs a baseline test, tests the connection of the cables, and identifies the dates of the most recent and next required calibrations.

It is not necessary to perform an Equipment Check regularly. When you call Natus Medical Technical Service or your authorized service representative, you may be asked to perform the check. More information about the three tests follows the instructions on running a test below.

Artifact Check

Myogenic interference can slow a screening. It can also be a frustrating problem to diagnose. If you are experiencing a lot of interference, use the Artifact Check to eliminate the baby as the problem and to check the screening device and environment independently.

When you do an Artifact Check, be sure the sensor cable clips are correctly attached to the Natus Medical ALGO Check Kit. Also, be sure to let the check run for at least 60 seconds before reading the result. The screener updates the result occasionally, so if you move the screener, or accidentally disconnect a clip, there may be a delay in the reading.

The outcome of the Artifact Check will be one of three conditions:

- **PASS**: This result indicates that the source of myogenic interference was the baby. Even a sleeping baby can generate myogenic interference. (See “Myogenic Interference” on page 65 for more information.)
- **FAIL**: This result indicates that either the environment or the screening device is the source of interference. Call Natus Medical Technical Service or your authorized service representative for help in determining other potential sources of interference.
- **PASS/FAIL**: If the display alternates between PASS and FAIL, the source of interference is not clear. Call Natus Medical Technical Service or your authorized service representative for help.

 © 2011 Natus Medical Incorporated

Acoustic Check

The Acoustic Check provides information about the integrity of the earphone cable. The Acoustic Check is neither a measurement nor an indication of the calibration status of the earphone cable.

Both right and left should pass.

- A **PASS** message indicates that the screener is not experiencing a failure and is operating properly.
- A **FAIL** message indicates a potential failure. Further testing must be done to determine the nature of the failure. Contact Natus Medical Technical Service or your authorized service representative.

Impedance Check

If you find a discrepancy between your screener's impedance measurements and what is listed in the text in the impedance check, contact Natus Medical Technical Service or your authorized service representative.

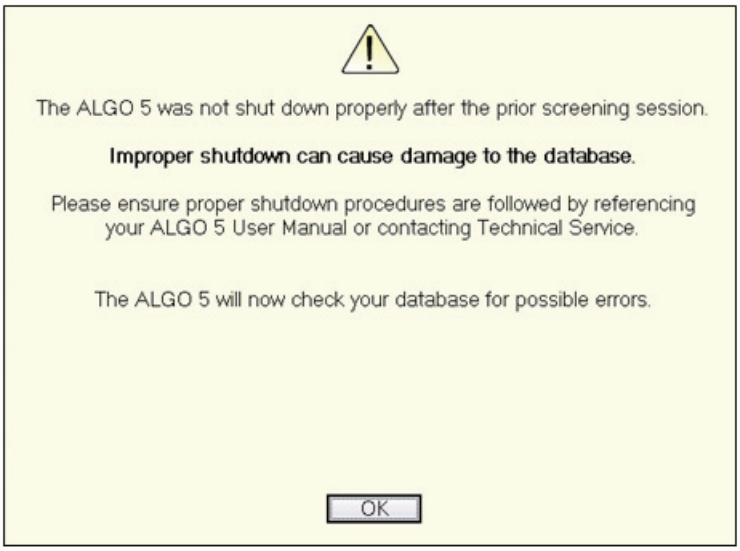
Database Corruption and Improper Shutdown Dialogs

IMPORTANT: The ALGO 5 must be shutdown properly as per Proper Shutdown Procedures page 49.

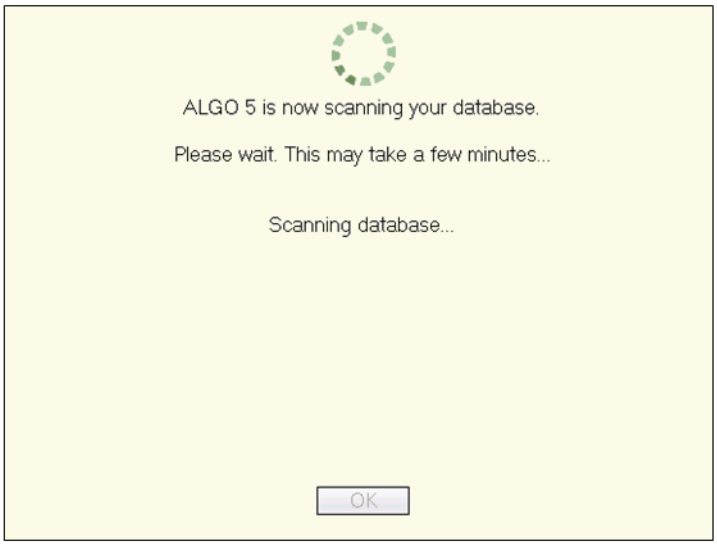
The ALGO 5 can detect if the device is improperly shutdown. The device has a database that requires proper shutdown to prevent corruption issues from occurring.

If an improper shutdown does occur, the ALGO 5 will alert the user upon the next startup of the device and then proceed to check the database for any possible errors.

The user will see the following screen:

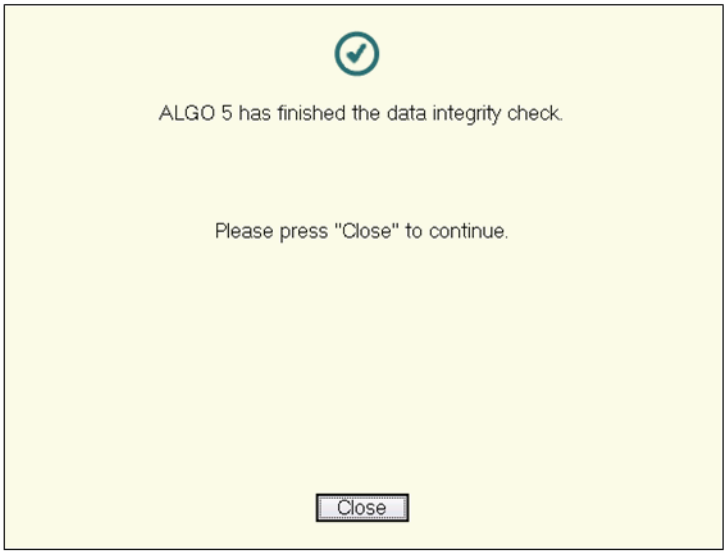

The ALGO 5 was not shut down properly after the prior screening session.
Improper shutdown can cause damage to the database.
Please ensure proper shutdown procedures are followed by referencing your ALGO 5 User Manual or contacting Technical Service.
The ALGO 5 will now check your database for possible errors.
OK

Upon pressing OK, the ALGO 5 will begin scanning the database and attempt to correct any errors that can be corrected.



The progress window may flash some updates as it proceeds. There is no need for the user to make note of these.

If the database is clean, the following message will appear:



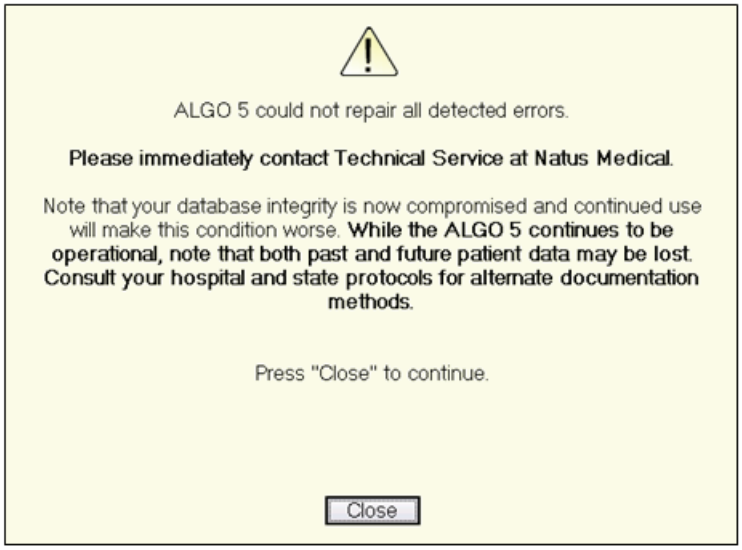
Press “Close” and then the system will instruct you to reboot and then start up normally.

IMPORTANT: Please ensure all staff are alerted to the need for proper shutdown.

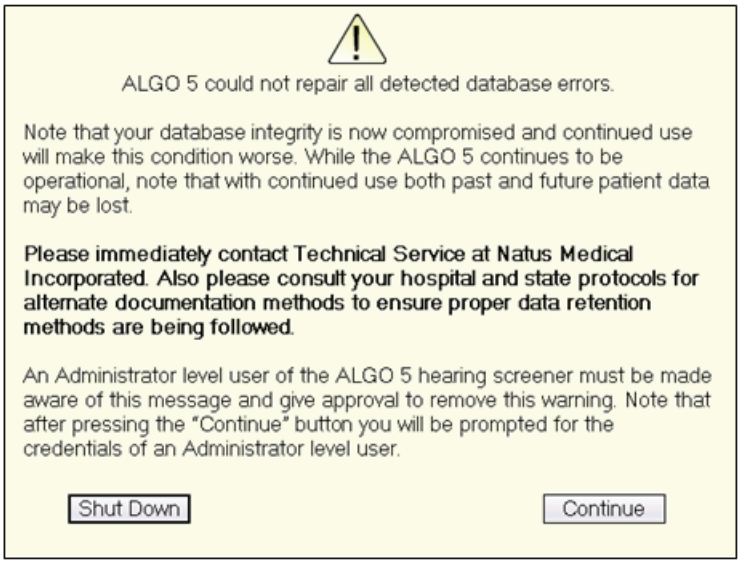
 © 2011 Natus Medical Incorporated

Corruption issues

However, if after the above data integrity check shows that the database has corruption issues and is not reparable, the following message will appear:


ALGO 5 could not repair all detected errors.
Please immediately contact Technical Service at Natus Medical.
Note that your database integrity is now compromised and continued use will make this condition worse. While the ALGO 5 continues to be operational, note that both past and future patient data may be lost. Consult your hospital and state protocols for alternate documentation methods.
Press "Close" to continue.
Close

At this point, please call Technical Service. Press "**Close**" and the following screen will appear:


ALGO 5 could not repair all detected database errors.
Note that your database integrity is now compromised and continued use will make this condition worse. While the ALGO 5 continues to be operational, note that with continued use both past and future patient data may be lost.
Please immediately contact Technical Service at Natus Medical Incorporated. Also please consult your hospital and state protocols for alternate documentation methods to ensure proper data retention methods are being followed.
An Administrator level user of the ALGO 5 hearing screener must be made aware of this message and give approval to remove this warning. Note that after pressing the "Continue" button you will be prompted for the credentials of an Administrator level user.
Shut Down
Continue

A user with administrator level access to the device must be made aware of the situation and give approval by entering their User Name and Password to continue use of the device.

Please evaluate your documentation protocols to ensure proper data retention.

If shutting down the device, press "**Shut Down**".

To continue using the device, press "**Continue**" and the following screen will appear:

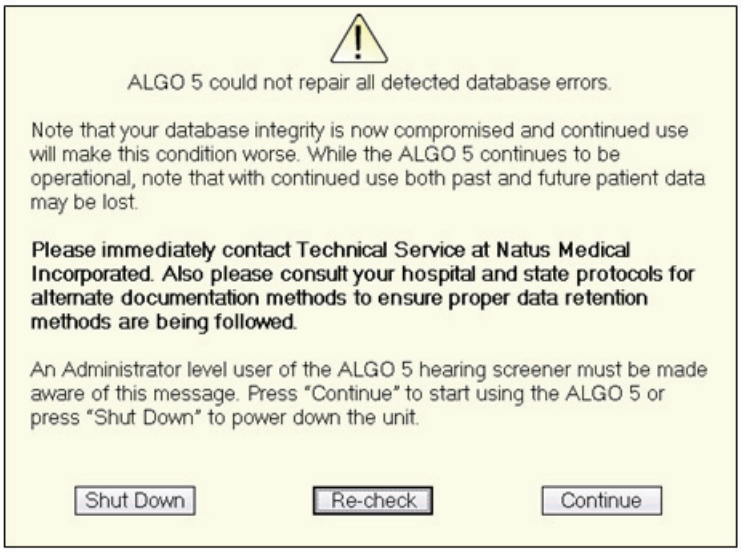
A user with administrator level access will need to enter their User Name and Password.

The system will proceed to the Main Window..

Subsequent uses of the device

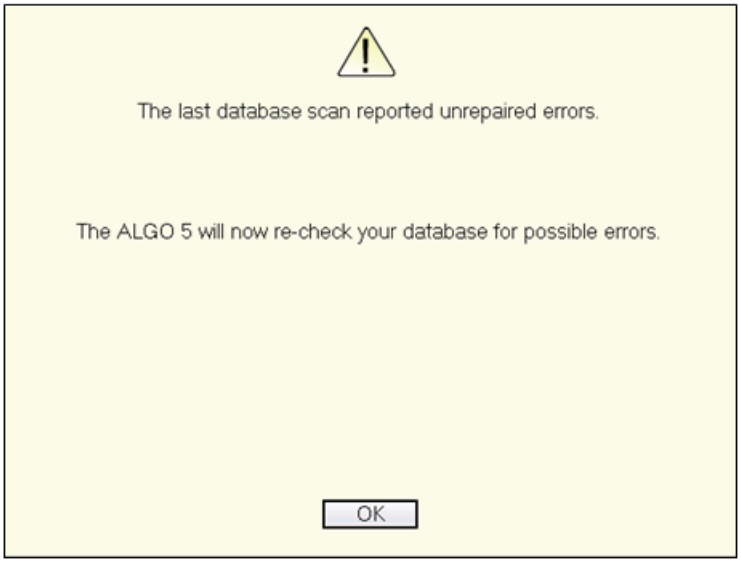
Note that at subsequent powering up of the device, existing database corruption will show a dialog similar to the initial warning including an additional option to re-check the database

 © 2011 Natus Medical Incorporated


ALGO 5 could not repair all detected database errors.
Note that your database integrity is now compromised and continued use will make this condition worse. While the ALGO 5 continues to be operational, note that with continued use both past and future patient data may be lost.
Please immediately contact Technical Service at Natus Medical Incorporated. Also please consult your hospital and state protocols for alternate documentation methods to ensure proper data retention methods are being followed.
An Administrator level user of the ALGO 5 hearing screener must be made aware of this message. Press "Continue" to start using the ALGO 5 or press "Shut Down" to power down the unit.
Shut Down
Re-check
Continue

Note: On subsequent database error warnings after the initial warning, the **Continue** option no longer requires an administrator login to proceed to screening.

If selected above, the re-check option will display the following screen and the process will proceed as above.



Update and Backup procedures

The ALGO 5 device will also check for database corruptions prior to performing either an Update or a Backup.

The device will guide you through the procedures as above with only minor wording differences in the onscreen dialogs that relate to the specific actions of Update or Backup.

 © 2011 Natus Medical Incorporated

Service and Maintenance

Periodic preventative maintenance of your ALGO® 5 Newborn Hearing Screener is required to ensure optimum performance and trouble-free operation. Simple maintenance of the hearing screener includes:

- Cleaning the Screener: see “Cleaning the Screener” on page 79
- Inspecting Accessory Parts (for wear): see “Inspecting Accessory Parts” on page 80
- Loading Printer Labels: see “Loading Printer Labels” on page 81
- Correcting a Printer Jam: see “Correcting a Printer Jam” on page 82
- Technical Service and Calibration: see “Technical Service and Calibration” on page 82

Cleaning the Screener

Clean the screener equipment according to your health facility’s protocol.

CAUTION: Before...

cycling the device power via the power switch on the column, or
unplugging the device, or
connecting or disconnecting cables, or
cleaning the device

...power off the device via the computer menu selections available. **Do not simply turn off the power switch nor unplug from the wall prior to a proper shutdown.**

The proper shutdown procedure includes navigating to the Main Window, choosing Exit and then either Power Off (and confirm your selection) or Hibernate.” Wait for the computer to complete the action chosen. Only then should the device be switched off via the switch at the bottom of the column, and then, if desired, be unplugged. Please refer to“Proper Shutdown Procedures” on page 53.

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures. Please refer to “Proper Shutdown Procedures” on page 53.

To keep the screener clean, perform the following tasks regularly:

- Remove dust from the screener’s exterior with a soft brush or cloth.
- Clean the exterior case of the screener with a lightly water dampened soft cloth.

- To clean the monitor display, dilute a volume of glass cleaner with an equal volume of water. Spray a small amount of the diluted cleaner on a soft cloth and gently wipe the screen.

CAUTION: Do not stretch the cables. Delicate shielding in the wires can be damaged, resulting in electrical shorting.

- Refer to your hospital's protocol for the frequency of cleaning equipment that comes into contact with the patient.
- Wipe off any remaining dirt or spots on the screener and cables with a cloth.

CAUTION: Do not spray or pour cleaners directly on the screener. Keep liquids, including cleaning fluid, away from the screener's keyboard and other openings. Never spray cleaner directly onto the screener. Never use harsh or abrasive chemical products to clean the screener. Do not immerse patient cables or transducers in water or cleaning solutions. Do not allow liquids to enter the holes on the transducer heads of the ATA cables as this may cause irreparable damage to the internal components.

Inspecting Accessory Parts

Routinely inspect screener components as described below:

- Inspect earphone cable for damage such as tears, cracks, evidence of liquid ingress, or exposed wires.
- Inspect sensor cable (PCA cable) for proper connection to the preamplifier box, for worn or broken insulation, and for looseness at the clips. Inspect preamplifier cable for damage.
- Inspect power cord for fraying or other damage.
- If the screener is frequently moved to different locations or subjected to heavy use, check regularly for external damage.
- Examine the preamplifier for cracks or dents, which might have been caused by repeated banging against the side of the screener or the edge of a crib.
- Replace accessories or have them repaired as needed.

⚠ **WARNING:** Do not use the screener if you suspect that it is not functioning properly, or if any parts appear damaged. Contact Natus Medical Technical Service or your authorized service representative.

 © 2011 Natus Medical Incorporated

Loading Printer Labels

CAUTION: Do not load printer labels while screening is in progress. Be sure you have paused the screen, or displayed the Main window while loading labels.

IMPORTANT: The Label Printer will automatically power on when a screen result requires printing.

To load new labels, use the following procedure:

1 Turn on screener and label printer.

2 Open printer label cover.

Swing open the smoke-colored plastic cover on the printer.

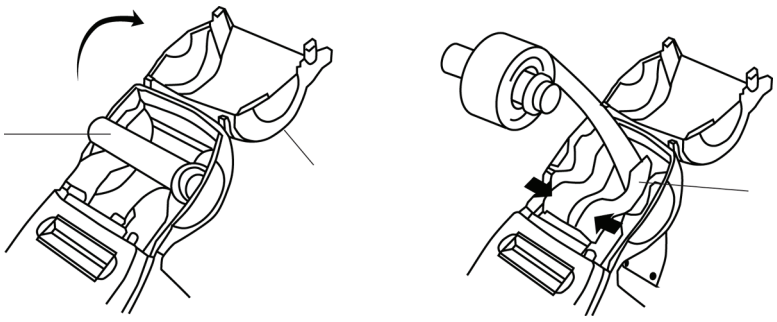
3 Remove empty roll.

Remove and discard the empty cardboard tube on the front face of the printer spool. Do not throw away plastic printer spindle.

4 Insert new label roll.

Place the roll of labels on the spool with the free edge coming off the bottom of the roll toward the printer (see figure).

Figure 31—Inserting Printer Labels



5 Feed label into slot and advance labels.

Place the free edge of the labels up against the label feed slot and press the label feed button. The labels will feed automatically.

6 Close printer label cover.

Swing close the plastic cover until it clicks into place.

Correcting a Printer Jam

Use the following procedure to clear the a jammed label.

> **Note:** It is safe to correct a printer jam without turning off the power to the screener. If you see the Printer Error display, you can correct the problem and then return to testing without losing your patient's screening results.

1 Open printer label cover.

Swing open the smoke-colored plastic cover on the printer.

2 Inspect for jammed labels and remove.

If you find a jammed label, gently pull label out (back toward the roll).

3 Press label feed button.

Tear off unusable labels and reposition the edge of the label roll in the label feed slot. Press the label feed button to advance labels.

4 Close printer label cover.

Swing the plastic cover closed, until it clicks into place.

5 Resume screening.

Select **Retry** to reprint the label or **Cancel** to return to the window you were using when the jam occurred.

Technical Service and Calibration

ALGO Screener Calibration Requirements

The ALGO Newborn Hearing Screener is a fully automated Auditory Brainstem Response (AABR) detection system. The screener itself does not require calibration or periodic maintenance.

The Acoustic Transducer Assembly (earphone cable) requires annual calibration. Annual calibration of the cable verifies and/or sets the intensity level of the click or output stimulus. Annual calibration is directly related to the ALGO screener's intended use: automatic operation by minimally trained personnel.

Earphone cable calibration may only be performed by a qualified representative of Natus Medical. For instructions on returning the earphone cable to Natus Medical, contact Natus Medical Technical Service.

 © 2011 Natus Medical Incorporated

Calibration Considerations

Please follow any procedures of your healthcare facility that are relevant to the calibration and maintenance of the ALGO screener. For instance, some professional organizations such as the American Speech-Language-Hearing Association (ASHA) have requirements for maintaining equipment according to the manufacturer's specifications.[2]

Other organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have strict guidelines for keeping calibration records on all equipment.[3]

Corrective Service/Maintenance

The ALGO screener does not require any routine service outside of earphone cable calibration. However, if the screener starts to malfunction or there are any questions regarding its performance, discontinue use and contact Natus Medical Technical Service. Corrective service and maintenance and all internal adjustments should be performed only by qualified Natus Medical personnel or authorized service representatives.

When calling for service, be sure to have the screener available. You may be asked by a technical service representative to perform simple system checks that require having the screener at hand.

⚠ **WARNING:** Do not remove the computer from the screening system unless your service representative specifically instructs you to do so. There are no user-serviceable parts inside the computer. Installation, modification, or replacement of any computer accessories, circuit cards, components, or alteration of the CMOS configuration memory may compromise the safe and effective operation of this device and will void the warranty.

Note: Consult the protocol of your healthcare facility for any additional information pertinent to the service of your ALGO screener.

2. American Speech-Language-Hearing-Association. (1997) Preferred Practice Patterns for the Profession of Audiology.

3. Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 2001 Hospital Accreditation Standards.

 © 2011 Natus Medical Incorporated

Preferences and Profiles

The ALGO® 5 screener is highly customizable. The software can be configured to reflect the particular needs of your institution.

The main Preferences menu consists of six choices: ALGO 5 Preferences, Data Management Preferences, Field Label Editor, User Manager, Profile Manager, and System Control. Each of these windows are described in this chapter:

- ALGO 5 Preferences: see “ALGO 5 Preferences” on page 86
- audble Data Management Preferences: see “audble Data Management Preferences” on page 91
- Field Label Editor: see “Field Label Editor” on page 102

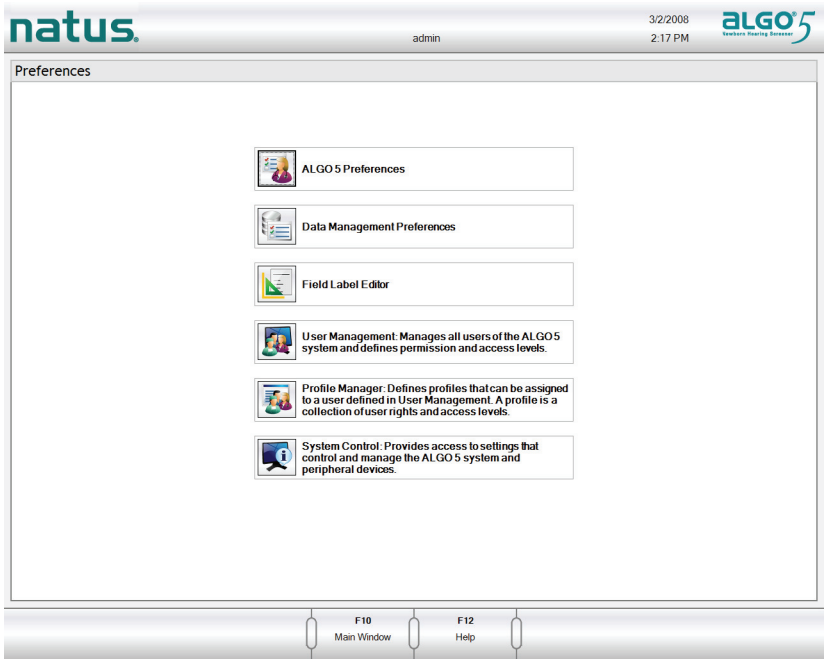
In addition, this section includes the following topics:

- User Management: see “User Management” on page 103
- Profile Manager: see “Profile Manager” on page 105
- System Control: see “System Control” on page 106

Note: The Preferences section is only available to users with administrator-level access.

To access the Preferences window, choose **Preferences (F4)** from the Main window. The following window will appear:

Figure 32—Preferences window


natus
admin
3/2/2008
2:17 PM
ALGO 5
Preferences
ALGO 5 Preferences
Data Management Preferences
Field Label Editor
User Management: Manages all users of the ALGO 5 system and defines permission and access levels.
Profile Manager: Defines profiles that can be assigned to a user defined in User Management. A profile is a collection of user rights and access levels.
System Control: Provides access to settings that control and manage the ALGO 5 system and peripheral devices.
F10
Main Window
F12
Help

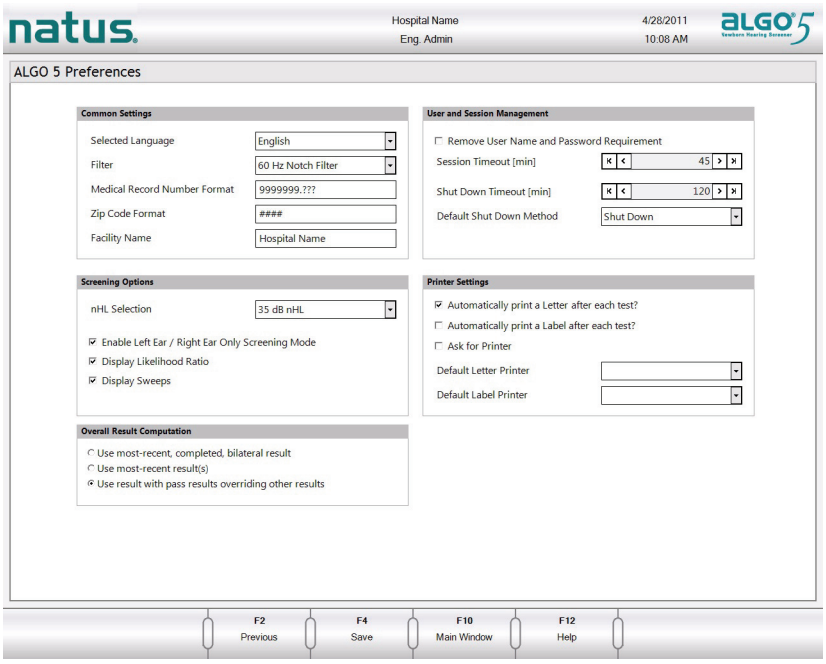
ALGO 5 Preferences

The ALGO 5 screener allows you to specify some of the parameters that appear on the Screening window as a screening occurs, as well as specify user and session management options and printer settings. These selections are made in the ALGO 5 Preferences window.

> **Note:** Use the tab key to move the cursor to each field on the ALGO 5 Preferences window.

To access the ALGO 5 Preferences window, select **Preferences (F4)** from the Main window, then select **ALGO 5 Preferences**. The following window will appear:

Figure 33—ALGO 5 Preferences window



There are five areas in the ALGO 5 Preferences window: Common Settings, Screening Options, User and Session Management, Printer Settings, and Overall Result Computation. Each of these areas is described below.

Common Settings

- Choose your preferred language using the pull-down menu.
- Choose your preferred notch filter (either 50 or 60 Hz) using the pull-down menu.

 © 2011 Natus Medical Incorporated

- Using the characters as described in the following table, specify the medical record format used by your hospital (e.g. 999-99-999 or aaa-99999). This will control the way that the user fills in this field when patient information is first entered.This feature helps in making the entry of this important patient identifier more consistent for tracking and data management.

Entering the Medical Record Format

Character	Description
#	Digit placeholder for mandatory numeric characters (0-9)
9	Digit placeholder for optional numeric char (0-9)
A	Placeholder for mandatory Alphanumeric character (a-z, A-Z, or 0-9)
a	Placeholder for optional Alphanumeric character (a-z, A-Z, or 0-9)
?	Placeholder for optional letters (a-z or A-Z)
Literal	All other symbols are displayed as literals; that is, they appear as themselves.
\A	\ Treat the next character in the mask string as a literal. This allows you to include the “#,” “&,” “A,” and “?” as well as other characters with special meanings in the mask.

- Specify a zip (postal) code format.
- Enter your facility name, if you would like it to be displayed at the top of the screen.

Screening Options

- Mark whether Left Ear/Right Ear Only Screening Mode should be available during the screening process.

  Note: Current screening recommendations (see JCIH 2007 Position Statement) are for bilateral screening including rescreens. For this reason, single ear screening methods are hidden as the default.

- Mark whether Likelihood Ratio (LR) should be displayed on the Screening window. Refer to the “Likelihood Ratio and Sweep Count” box on the following page for more information on likelihood ratio.
- Mark whether sweeps should be displayed on the Screening window. Refer to the “Likelihood Ratio and Sweep Count” box on the following page for more information on sweeps.

Likelihood Ratio and Sweep Count

The sweep count is the number of “acceptable” sweeps accumulated by the screener. A single sweep is one instance in which the screener generates a click and collects usable data in response to that click. The screener updates the sweep count in real time.

Usable reading during a screening accumulate at a slower rate as noise or interference increases. The screener accumulates sweeps at a faster rate as noise or interference decreases. Impedance readings are updated periodically. During a screening, high impedance will only be displayed as an alarm message (i.e. sensors flashing red, baby illustrations flashing red), at each scheduled update. If a screening pauses due to high impedance, the screener will discard all data accumulated since the last update. The screener resets the sweep count to the last update.

The Likelihood Ratio (LR) is a numerical representation of the screener’s progress towards generating a PASS result. As a screening proceeds, the LR value increases, indicating that the screener is gaining statistical confidence towards a PASS result. In some instances, the LR value will decrease to indicate that the screener is losing statistical confidence. If a PASS result is generated, the LR value will be 160 or greater. If a REFER result is generated, the LR value will be less than 160. The screener updates the LR value periodically.

> **Note:** Sweep counts and likelihood ratio only display on the Screening window if they are designated on the ALGO 5 Preferences window. Sweep counts are always printed on the results label. Likelihood ratio is never printed on the results label.

Displaying the sweeps is not necessary, however the sweep count does give an indication of how far the screening has progressed for a particular patient. The sweep count also indicates when the screening is slowing down as a result of excessive interference. Likewise, it is not necessary to display LR, but with a combination of the sweeps and LR, a user can evaluate the relative progress of the procedure. (Refer to “Running the Screening Procedure” on page 45.)

User and Session Management

- Place a check mark next to “Disable User Management” if you do not want to require password-protected login for users. (See “User Management” on page 103 for more information.)
- Select timeout values for session and shutdown.
- Use the “ **<** “ and “ **>** “ arrow buttons to move up or down in 10-minute increments. Use the “ **|<** “ and ” **>|** ” arrow buttons to select the minimum or maximum time allowed.

 © 2011 Natus Medical Incorporated

Note: Session timeout value must be between 30 and 300 minutes. Shutdown timeout must be between 30 and 600 minutes. Shutdown timeout must be greater than session timeout.

Printer Settings

- Mark whether labels or letters should print out automatically at the end of each test. Mark “Ask for printer” if you would like the screener to prompt the user to print a label or letter.
- Use the pull-down menus to select the default label and letter printers.

After completing the ALGO 5 Preferences window, select **Save (F4)** to save all entries. Once all entries are saved, the “Save” button will become inactive (faded out). Select **Previous (F2)** to return to the main Preferences window, or select **Main Window (F10)** to return to the Main window.

Overall Result Computation

The ALGO 5 uses a patient-centric data management logic and displays or prints a single “overall result” for each patient. The method of computation for this Overall Result will depend upon the option chosen by the program administrator in setting User Preferences at the time of installation. Based upon the option chosen and the number of screenings performed on an individual infant, the Overall Result can represent a combination of pass and/or refer results from multiple screenings when it is displayed in the following:

- Multi-Patient View window
- Patient Reports and Letters
- Statistical Reports

IMPORTANT: These settings cannot affect the clinical result obtained from the ALGO 5 device from a single screening. These settings do not affect the results printed on the results label.

Note: Consult your hearing screening program supervisor for hospital protocols regarding these settings. State or regional newborn hearing screening program coordinators can advise which option complies with relevant requirements.

The Overall Result Computations settings are:

- **Option 1: Use last completed bilateral result from simultaneous or sequential test modes only.** This setting is the default. Results obtained from a single ear test or where a test is not completed will be excluded from the overall result determined by audble® Data Management. See the examples that follow.

  It is important to recognize the implications of communicating an overall result calculated in this manner. Use of multi-patient views, statistical reports, or patient reports instead of single test labels, or single patient editing screens may lead to communication of a “PASS” overall result by overriding other results (that is, a Refer, an Incomplete, or a Not Tested), as the following examples illustrate:

Baby A Screening	Left	Right
#1: Jan 1 (simultaneous or sequential screen)	Refer	Pass
#2: Jan 1 (simultaneous or sequential screen)	Pass	Pass
Overall Result	**PASS**	**PASS**

Baby B Screening	Left	Right
#1: Jan 1 (simultaneous or sequential screen)	Pass	Pass
#2: Jan 7 (single ear result)	Refer	Incomplete or Not Tested
Overall Result	**PASS**	**PASS**

- **Option 2: Most recent single ear result, excluding "Incomplete" or "Not Tested" results.** Using this option combines left ear results and right ear results obtained from simultaneous, sequential, and single ear tests.

Screening	Left	Right
#1: Jan 1	Refer	Pass
#2: Jan 1(single ear result)	Pass	Incomplete or Not Tested
Overall Result	**PASS**	**PASS**

- **Option 3: Pass OverridesRefer: Continues the current software version 1.2 and lower combined result.** This setting utilizes all screening types and results (single ear, simultaneous, sequential, pass, refer, incomplete, not tested) and sets the patient's result as the highest ranking individual result for each ear based on the following order: (1) Pass, (2) Refer, (3) Incomplete, (4) Not tested.

  Note: The patient result derived from this setting can be combined from different screening sessions. For example, in a case where a single ear Pass result was obtained for a patient during an earlier screening session, a subsequent Refer result on that ear would be overridden.

Screening	Left	Right
#1	Refer	Pass
#2	Pass	Refer
Overall Result	**PASS**	**PASS**

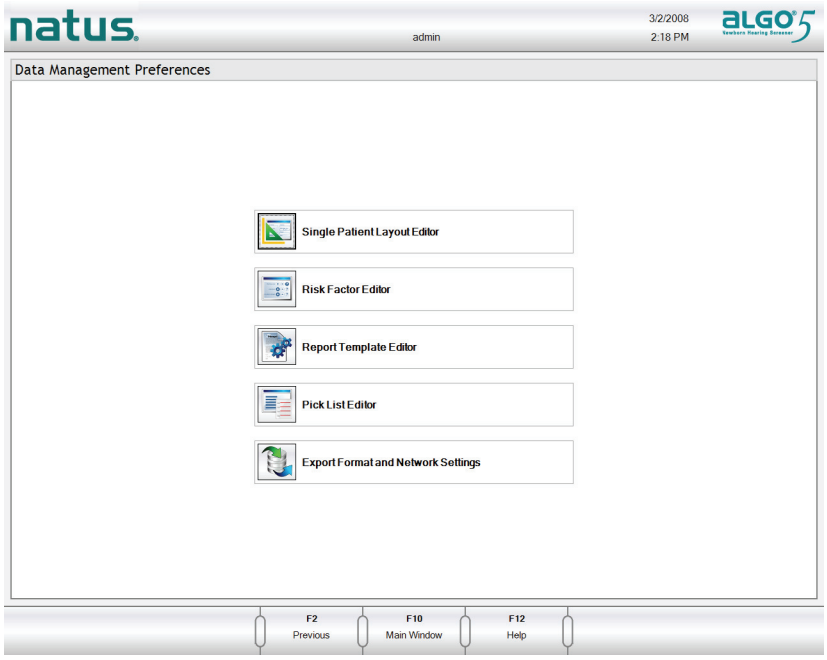
 © 2011 Natus Medical Incorporated

audble Data Management Preferences

The audble Data Management Preferences allows you to customize the patient information window, edit the list of risk factors, pre-format letters and reports, create a pick list, and designate your data management settings.

To access the audble Data Management Preferences window, first select **Preferences (F4)** from the Main window, then select **Data Management Preferences**. The following window will appear:

Figure 34—Data Management Preferences window



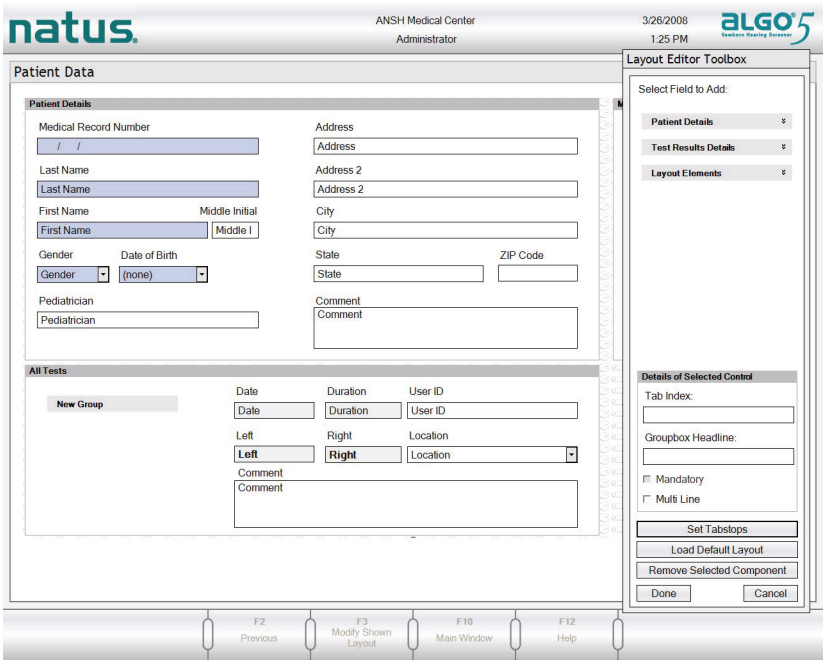
Single Patient Layout Editor

The Single Patient Layout Editor allows you to customize the contents of the Patient Data window, and also allows you to designate which fields are mandatory.

> **Note:** The type of patient information to be captured with each screening should be established in your healthcare facility's protocol.

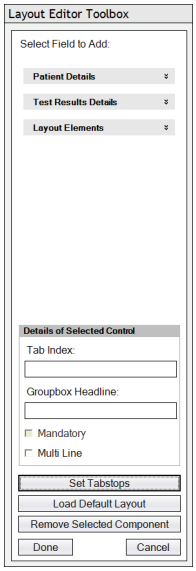
To access this window, select **Single Patient Layout Editor** from the Data Management Preferences window. The following window will appear:

Figure 35—Single Patient Layout Editor



The Single Patient Layout Editor shows the current layout of the Patient Data window. To make changes to the layout, select **Modify Shown Layout (F3)**. The Layout Editor Toolbox will appear:

Figure 36—Layout Editor Toolbox



The layout consists of fields grouped by category within boxes. You can add or delete both fields and groupboxes, or customize the location, size, and options of the fields and groupboxes.

 © 2011 Natus Medical Incorporated

Adding New Fields

To add a new field object:

1 **Select a field from the lists in the Layout Editor Toolbox.**

2 **Position the pointer in the area of the layout where you would like the new field to be, and click once. The field and its header will appear.**

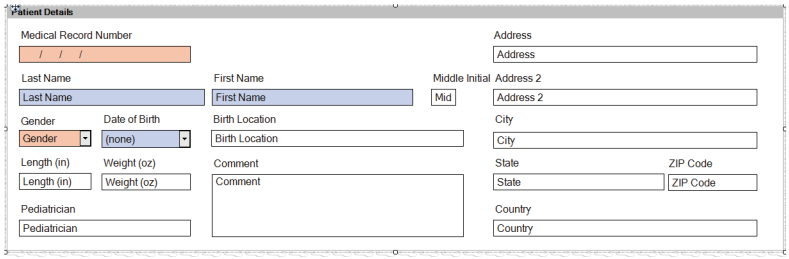
Note: Do not “click and drag” fields.

Now that the field exists, you can resize it, relocate it, or set its options. See below for details.

Selecting Fields or Groupboxes

To do anything with a field or groupbox (resize it, move it, delete it, etc.), you first have to select it. When a field is selected, the object frame displays handles on its right and left edges if it is a single-line field, and all four edges and four corners if it is a multi-line field. The object frame will also be highlighted with an additional dotted outline. These handles and outline indicate that the field is selected, and therefore active.

Figure 37—“Active” groupbox showing dotted outline and handles.



1 **Position the pointer inside the object frame and click once. The resizing handles appear, indicating that you have selected the object.**

2 **Move the pointer away from the object frame and click in an empty part of the window. The handles disappear.**

Deleting Fields or Groupboxes

To delete fields or groupboxes:

1 **Select the field or groupbox object that you would like to delete.**

2 **Select Remove Selected Component in the Layout Editor Toolbox.**

Note: When you delete a Group Box Frame object, the enclosed fields are automatically deleted.

Relocating and Resizing Fields

Fields are grouped by category (e.g. Patient Details, Mothers Details, and All Tests). You may change the location of fields within their groupbox, but you cannot move fields from one groupbox to another.

The resize handles indicate the direction in which fields can be resized. Single-line fields can only be resized horizontally; multi-line fields can be resized both horizontally and vertically.

1 **Select the field that you would like to relocate by clicking within the field.**

2 **Relocate the field by clicking in the center of the field and dragging it to your desired location.**

Note: Move the field and field heading at the same time by using the CTRL-click combination to select both objects.

3 **Resize the field by dragging one of the resize handles.**

Relocating and Resizing Groupboxes

When you relocate a groupbox, you also automatically relocate all the fields within that groupbox.

1 **Select the groupbox that you would like to relocate by clicking inside the box.**

2 **To relocate the groupbox, drag the location handle.**

3 **To resize the groupbox, drag one of the resize handles.**

Note: When you resize a groupbox, the enclosed fields do not resize. Be sure that you do not set the box's size smaller than the enclosed fields, or the enclosed fields will not display.

Setting Field Options

To set the options for each field:

1 **Select the field that you would like to modify by clicking within the field.**

2 **Change the Tab Index number, if desired.**

(For details, see "Understanding Tab Index Numbers" on page 95.)

3 **Mark whether the field is mandatory.**

Note: If a field is labelled "mandatory," the user cannot proceed with a screening until information is entered into that field.

4 **Mark whether the field is multi-line.**

 © 2011 Natus Medical Incorporated

Setting Groupbox Options

To set the groupbox options:

1 **Select the groupbox that you would like to modify**

2 **Change the Tab Index number, if desired.**

(For details, see “Understanding Tab Index Numbers” on page 95.)

3 **Enter your desired title into the Groupbox Headline field.**

> **Understanding Tab Index Numbers**
>
> During patient data entry, the user can hit the “Tab” key to move from field to field, rather than manually selecting each field with a pointer device. The Tab Index number controls the order in which these fields become active as the user hits the “Tab” key. The software comes installed with default settings for both groupbox and field Tab Index numbers. You may change the Tab Index settings to better fit the needs of your healthcare facility, if desired.

Saving or Removing Changes

To save your changes:

1 **Select Done in the Layout Editor Toolbox. The Data Management Layout window will now display your modified layout.**

To return to the default layout:

1 **Select Modify Shown Layout from the Data Management Layout window, then select Load Default Layout from the Layout Editor Toolbox.**

IMPORTANT: Selecting **Load Default Layout** will remove all changes that you have made.

When you are finished with the Single Patient Layout Editor, select **Previous (F2)** to return to the Data Management Preferences window, or select **Main Window (F10)** to return to the Main window.

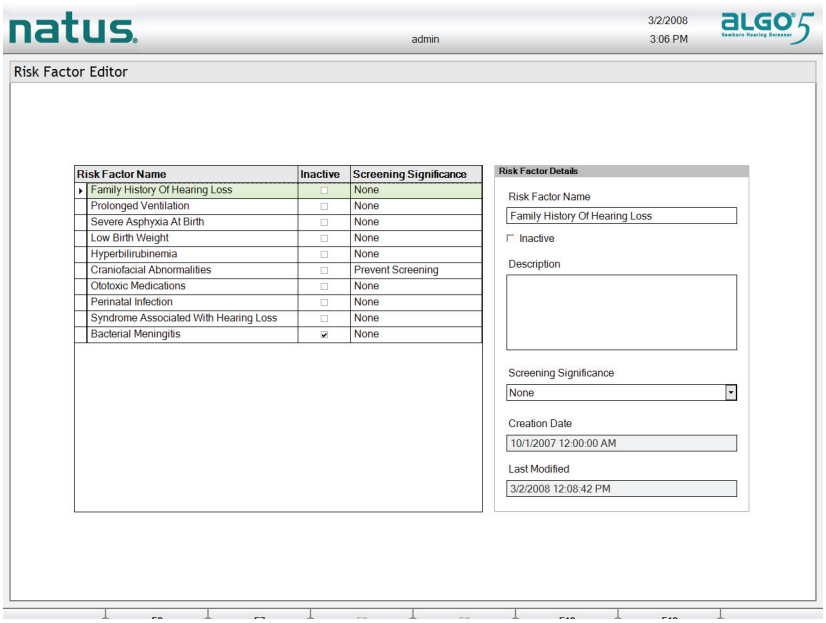
Risk Factor Editor

The Risk Factor Editor allows you to customize which risk factors appear in the Risk Factor Selection window during screening, and also allows you to enter new risk factors.

> **Note:** Refer to your health facility’s protocol for guidance on which risk factors should be included or added. If they are not displayed for patient entry, risk factors will be recorded in audble Data Management as “Unknown.”

To access this window, select **Risk Factor Editor** from the Data Management Preferences window, and the following window will appear:

Figure 38—Risk Factor Editor



Editing Risk Factors

To edit a risk factor:

1 **Highlight a risk factor in the list on the left side of the window.**

2 **In the Risk Factor Details box, make changes as necessary:**

a You may edit the name of the risk factor.

b Mark the “Inactive” box if you do not want the risk factor to appear in the Risk Factor Selection window during the screening process.

c Enter a description of the risk factor in the text box if desired.

d If the risk factor should prevent a screening, select “Prevent Screening” from the Screening Significance pull-down menu.

Note: During the screening process, if a risk factor is marked “**+**,” and the risk factor has been designated with the significance of “Prevent Screening,” the user will not be able to proceed with the screening.

3 **Select Save Risk Factor (F7) to save your changes.**

Note: The Creation Date and Last Modified fields are filled in automatically.

 © 2011 Natus Medical Incorporated

Adding New Risk Factors

To add a new risk factor to the list:

1 **Select Add New Risk Factor (F7)**

2 **In the Risk Factor Details box, make changes as necessary:**

a You may edit the name of the risk factor.

b Mark the “Inactive” box if you do not want the risk factor to appear in the Risk Factor Selection window during the screening process.

c Enter a description of the risk factor in the text box if desired.

d If the risk factor should prevent a screening, select “Prevent Screening” from the Screening Significance pull-down menu.

Note: During the screening process, if a risk factor is marked “+,” and the risk factor has been designated with the significance of “Prevent Screening,” the user will not be able to proceed with the screening.

3 **Select Save Risk Factor (F7) to save your changes.**

Note: The Creation Date and Last Modified fields are filled in automatically.

Deleting Risk Factors

To delete risk factors from the list:

1 **Highlight a risk factor in the list on the left side of the window.**

2 **Select Delete Risk Factor (F9)**

Note: Only risk factors that have been added to the list may be deleted, and a risk factor that has been used cannot be deleted. None of the risk factors in the default list may be deleted.

When you are finished with the Risk Factor Editor, select **Previous (F2)** to return to the Data Management Preferences window, or select **Main Window (F10)** to return to the Main window.

Report Template Editor

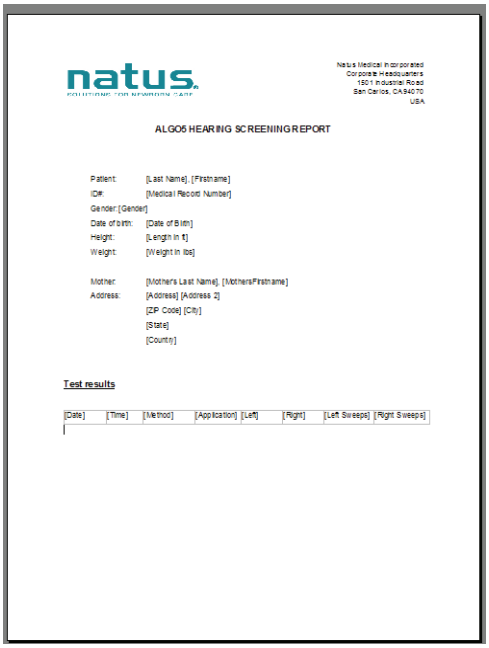
The ALGO 5 is highly customizable. The reports and letters that are included in the software can be customized to best fit the specific needs of your health facility. Although you cannot create new letters and reports, you can modify the existing ones and save your changes. You may change the text of the letters, add or delete data fields, or add images (such as your health facility’s logo).

Adding Your Health Facility’s Information

The letter/report templates included with your ALGO 5 have placeholders for your facility logo and address. You may insert your logo and address, if desired. If you will be printing reports and letters on your facility’s letterhead, you may

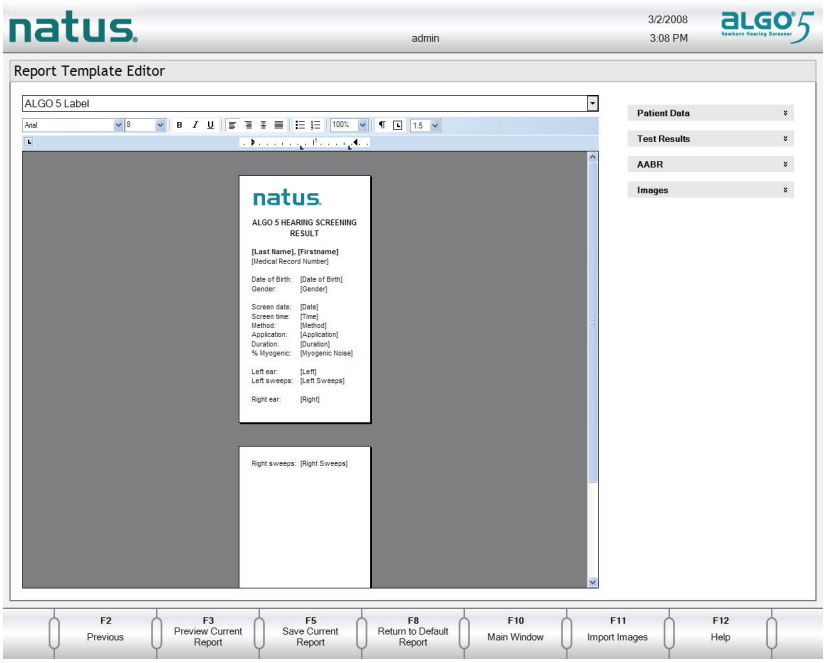
choose to leave the logo and address areas of the template blank. A example of a report template showing the Natus Medical logo and address is below. Instructions for adding your own information follow in this section.

Figure 39—Report template with logo and address added



To access this window, select **Report Template Editor** from the Data Management Preferences window. The following window will appear:

Figure 40—Report Template Editor



 © 2011 Natus Medical Incorporated

To format reports and letter templates:

1 **Select the report or letter that you wish to edit from the pull-down menu at the top of the screen.**

a This brings up the report or letter template. The Field Tree to the right contains components for building a report, such as data fields and images. These components are categorized as follows: Patient Data, Overall Test Result, Test Results, AABR, Tables and Grids, and Images

Note: The component categories available will change depending on which report is being edited. Not all component categories will be available for every report template.

b Click the arrows on the right side of the category header boxes to expand and contract the category lists.

2 **To add a component to the template, select an item from the list, click on the field and drag it to the appropriate position on the report template panel on the left.**

You may repeat this process to add as many fields as needed.

Note: Use an “Image” component to import your facility logo.

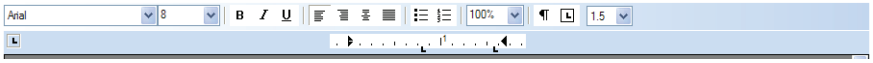
3 **You may edit the font, size, style, alignment, and spacing of body text or data fields.**

a Select the text and fields that you want to edit.

b Use the text formatting bar (shown below) to make edits.

c The template will reflect your changes.

Figure 41—Report Template Editor: Text Formatting Bar



4 **To delete fields or text, select the fields or text and use the “delete” or “backspace” key on the keyboard.**

5 **You may edit the content of letters by typing in the template.**

6 **To preview your changes, select Preview Current Report (F3).**

7 **When you are finished with your changes, select Save Current Report (F5).**

8 **To remove all changes and revert to the default version of the report, select Revert Current Report (F8).**

Note: Choosing to “Revert Current Report” will delete all changes ever made to a report. The template will revert to the default version of the report that was originally included with the software.

When you are finished with the Report Template Editor, select **Previous (F2)** to return to the Data Management Preferences window, or select **Main Window (F10)** to return to the Main window.

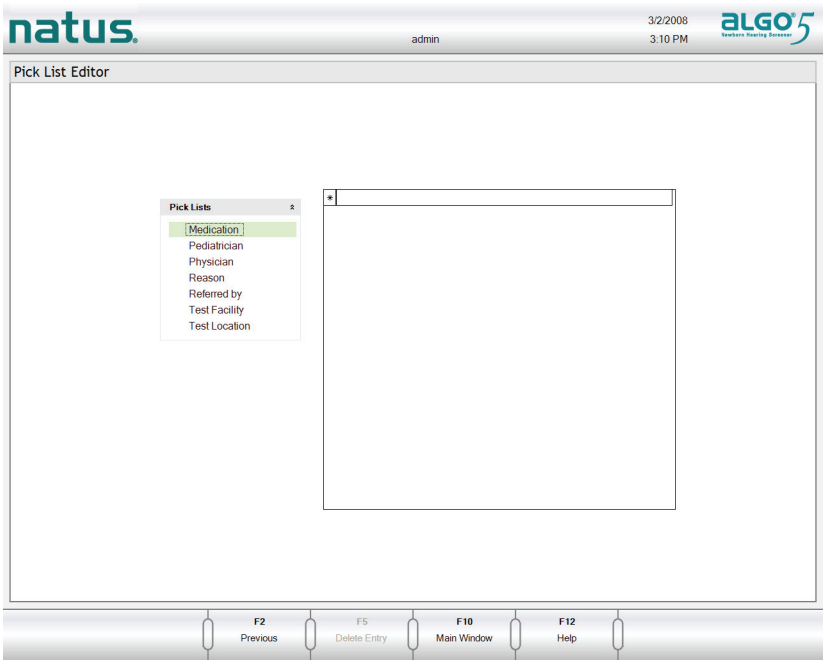
Note: The footer text as shown in print preview of a letter or report can be changed in the Field Label Editor from the main Preferences screen.

Pick List Editor

The Pick List Editor is used to create lists used in pull-down menus for data entry fields in the Patient Data window. You may create lists for Medication, Pediatrician, Physician, Reason, Referred By, Test Facility, and/or Test Location.

To access the Pick List Editor, select **Pick List Editor** from the Data Management Preferences window. The following window will appear:

Figure 42—Pick List Editor



To create pick lists:

1 **Highlight a Pick List from the list on the left.**

2 **Click once in the top data entry field on the right, so that a text cursor appears in the field.**

3 **Enter an item for the list, then hit Tab to move to the next data entry field.**

4 **To delete entries, highlight an item in the list by clicking in the box to the left of the item name. An arrow will appear next to the name. Select Delete Entry (F5).**

 © 2011 Natus Medical Incorporated

5 When you are finished entering items for one pick list, highlight another pick list from the list to create another list.

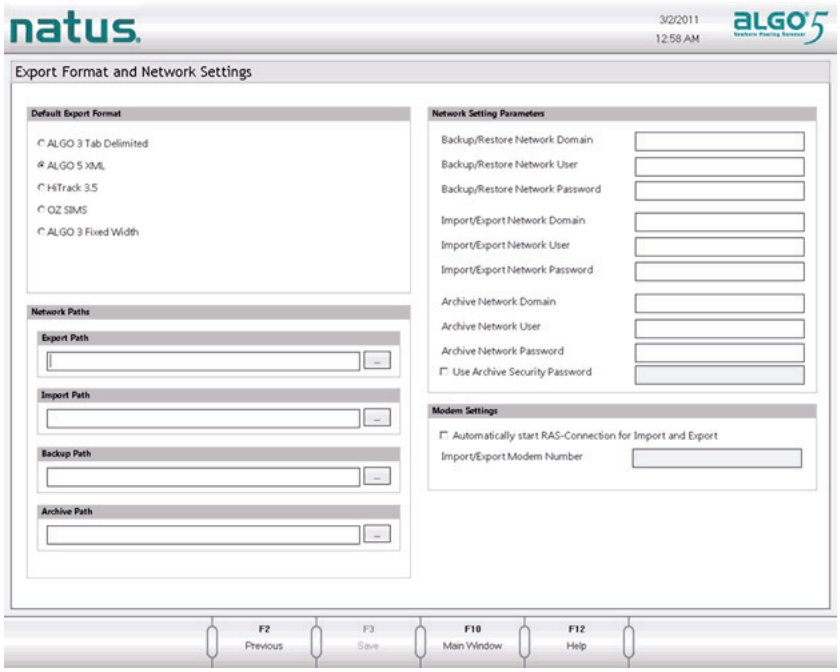
Note: There is no need to save your lists. Entries are automatically saved.

When you are finished with the Pick List Editor, select **Previous (F2)** to return to the Data Management Preferences window, or select **Main Window (F10)** to return to the Main window.

Export Format and Network Settings

The Export Format and Network Settings window is used to define formats, paths, and parameters for data import, data export, and network settings. To access this window, select **Export Format and Network Settings** from the Data Management Preferences window. The following window will appear:

Figure 43—Export Format and Network Settings window



To define settings:

1 Select the default format for exported data: ALGO 3 Tab Delimited, ALGO 5 XML, HiTrack 3.5, HiTrack 4.0, or OZ SIMS.

Select the default data-export format. This will set the default format when saving results. A file in Tab-delimited format allows direct comparison with data from an ALGO Model 2e Color screener. The export files from the ALGO 5 screener are text-based and unencrypted.

2 **Define the default export, import, and backup network paths.**

Use the " ... " buttons to the right of the data fields to browse to the preferred locations.

Note: The names of these paths need to follow Universal Naming Convention (UNC) rules.

Note: You cannot save a path to a USB or CD drive, but these drives will appear as an option during import or export if they are connected to your system.

3 **Define the domain, user, and password information for both backup/restore and import/export network locations, if desired.**

These settings may not be necessary; for example, if you are backing up to a CD.

4 **When you are finished entering information, select Save Changes (F3).**

If you leave the window without selecting Save Changes, your changes will be discarded.

5 **Select Previous (F2) to return to the Data Management Preferences window, or select Main Window (F10) to return to the Main window.**

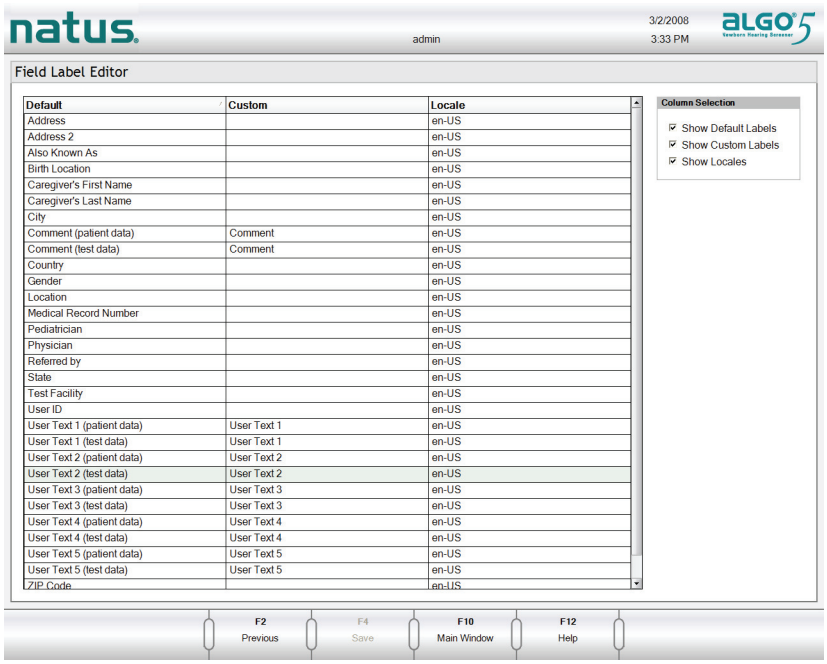
Field Label Editor

The Patient Data window is highly customizable. Field labels can be altered to reflect the terminology used in a specific institution. For example, the "Medical Record Number" field can be changed to "Patient ID." There are also field labels designated as "User Text" that can be set to any label a user may desire.

To access this window, select **Preferences (F4)** from the Main Window, then select **Field Label Editor** from the main Preferences window. The following window will appear:

 © 2011 Natus Medical Incorporated

Figure 44—Field Label Editor window



To edit field labels:

1 **From the Main window, select Preferences (F4), then select "Field Label Editor."**

2 **Find the label to change in the "Default" column.**

3 **Click on the cell in the corresponding Custom column in the same row.**

4 **Type in the text to replace the default ALGO 5 text.**

5 **Click elsewhere in the screen to remove the cursor from the field being edited.**

6 **When you are finished entering your custom text, select Save (F4).**

The edited label(s) will now be reflected in the Patient Data window.

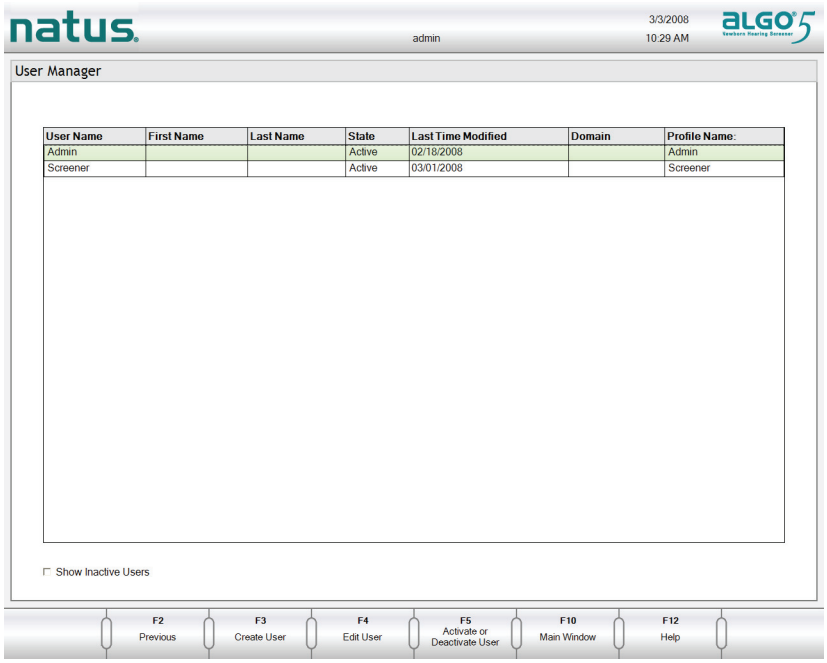
User Management

The User Management preference allows the administrator to create users and define their rights and access levels using pre-defined profiles.

Note: The ALGO 5 must be populated with users to allow accounts to utilize the security and auditing functionalities of the device.

To access this window, select **Preferences (F4)** from the Main Window, then select **User Management** from the main Preferences window. The following window will appear:

Figure 45—User Management window



Create new user

1. **Select Create User (F3).**
2. **Enter a user name.**
3. **Enter the Last Name and First Name of the user (if desired).**
4. **Choose a profile to be assigned to this user.**

   See “Profile Manager” on page 105 for more information on Profiles.
5. **Enter a password for this user. Re-enter the password.**
6. **Select Save (F3).**

Note: Do not create new users with the names "Admin" or "Screener" as it will cause problems with the ALGO 5 device's User Management system.

Edit User

A user's information or password can be changed by the administrator. To edit an individual user:

1. **Highlight a user by clicking in the row for that user record, then select Edit User (F4).**
2. **Edit the existing information, add new information, or create a new password.**
3. **When you are finished editing the user information, select Save (F3).**
4. **Select Previous (F2) to return to the User Manager window.**

 © 2011 Natus Medical Incorporated

Activate or Deactivate User

A user can be deactivated if the user is no longer desired to have access. This can be changed later by activating a deactivated user.

To activate or deactivate a user:

1 **Highlight a user by clicking in the row for that user record, then select Activate or Deactivate User (F5).**

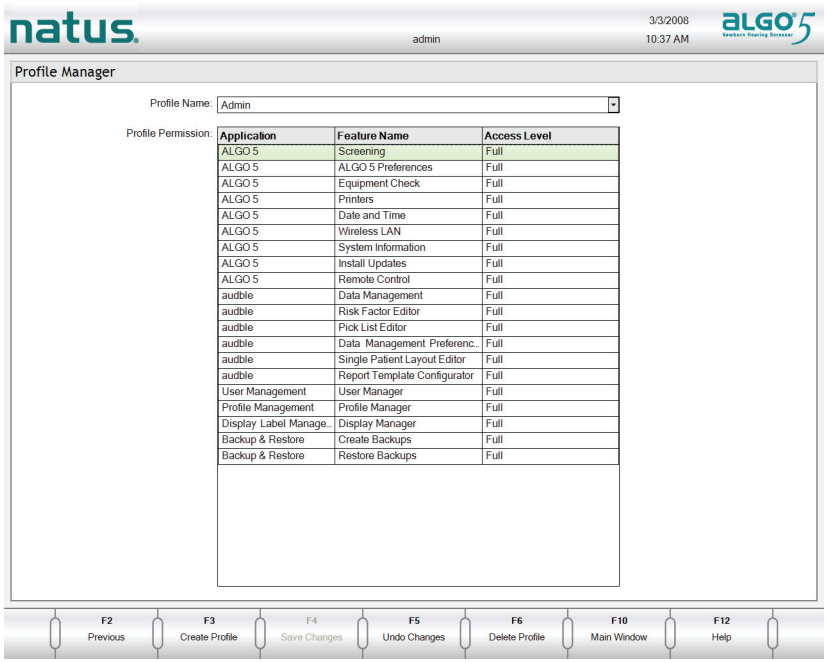
Check the “Show Inactive Users” box in the lower right corner of the User Manager screen to display users that are inactive.

Profile Manager

The Profile Manager is used to define all profiles that can be assigned to a user in the User Manager window. A profile is a collection of user rights and access levels. The ALGO 5 has two default profiles: Administrator and Screener. The default profiles cannot be altered, but you can create any number of custom profiles.

To access this window, select **Preferences (F4)** from the Main Window, then select **Profile Manager** from the main Preferences window. The following window will appear:

Figure 46—Profile Manager window


natus
admin
3/3/2008
10:37 AM
ALGO 5
Profile Manager
Profile Name: Admin
Profile Permission:
Application | Feature Name | Access Level
ALGO 5 | Screening | Full
ALGO 5 | ALGO 5 Preferences | Full
ALGO 5 | Equipment Check | Full
ALGO 5 | Printers | Full
ALGO 5 | Date and Time | Full
ALGO 5 | Wireless LAN | Full
ALGO 5 | System Information | Full
ALGO 5 | Install Updates | Full
ALGO 5 | Remote Control | Full
audible | Data Management | Full
audible | Risk Factor Editor | Full
audible | Pick List Editor | Full
audible | Data Management Preferenc.. | Full
audible | Single Patient Layout Editor | Full
audible | Report Template Configurator | Full
User Management | User Manager | Full
Profile Management | Profile Manager | Full
Display Label Manage.. | Display Manager | Full
Backup & Restore | Create Backups | Full
Backup & Restore | Restore Backups | Full
F2 Previous
F3 Create Profile
F4 Save Changes
F5 Undo Changes
F6 Delete Profile
F10 Main Window
F12 Help

Create New Profile

To create a new profile:

1 **From the Profile Manager window, choose Create Profile (F3).**

2 **Type the name of the new profile into the Profile Name field.**

3 **Click in the cells in the "Access" column to edit the access levels for each application and feature.**

4 **Select Undo Changes (F5) to reset access levels to the default.**

5 **When you are finished defining the profile access levels, select Save Changes (F4).**

You may choose **Delete Profile (F6)** to delete custom profiles. Profiles that have been applied to a user cannot be deleted.

Edit Profiles

To edit an existing profile:

1 **From the Main window, select Preferences (F4), then Profile Manager.**

2 **Choose the profile to edit, using the pull-down menu at the top of the window.**

3 **Choose the application and feature to edit.**

4 **Click on the corresponding cell in the "Access" column to change the access level.**

Note: The default ALGO 5 profiles cannot be deleted or edited.

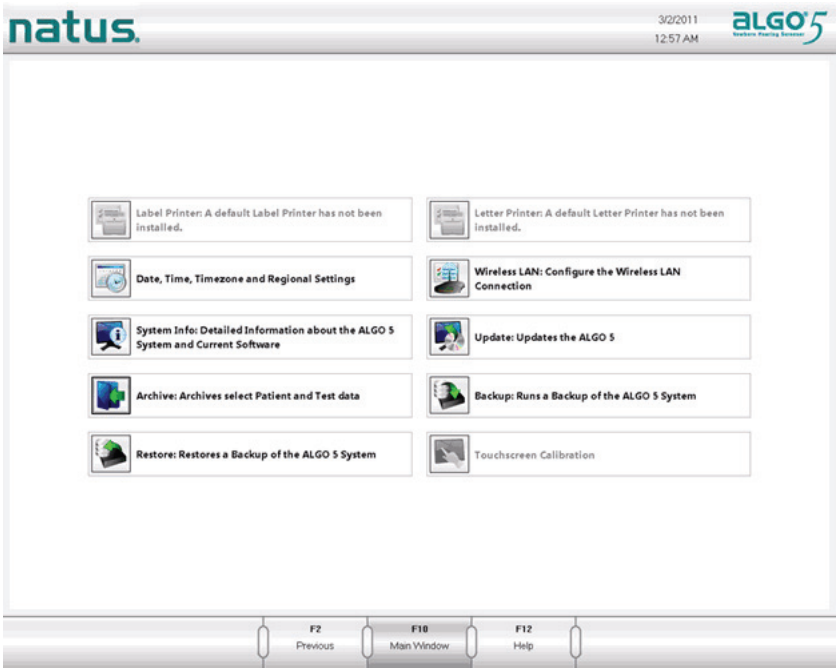
System Control

The System Control window provides several features to control and manage the ALGO 5 computer system. Each of these features is described below.

To access this window, select **Preferences (F4)** from the Main Window, then select **System Control** from the main Preferences window. The following window will appear:

 © 2011 Natus Medical Incorporated

Figure 47—System Control window


natus
3/2/2011
12:57 AM
ALGO 5
Label Printer: A default Label Printer has not been installed.
Letter Printer: A default Letter Printer has not been installed.
Date, Time, Timezone and Regional Settings
Wireless LAN: Configure the Wireless LAN Connection
System Info: Detailed Information about the ALGO 5 System and Current Software
Update: Updates the ALGO 5
Archive: Archives select Patient and Test data
Backup: Runs a Backup of the ALGO 5 System
Restore: Restores a Backup of the ALGO 5 System
Touchscreen Calibration
F2
Previous
F10
Main Window
F12
Help

Label Printer

The ALGO 5 includes a label printer as part of the standard package. Use the Label Printer window to set up this printer.

To access this window, select **Label Printer** from the System Control window.

Letter Printer

An optional letter-size printer is available for printing letters and reports. Use the Letter Printer window to set up this printer.

To access this window, select **Letter Printer** from the System Control window.

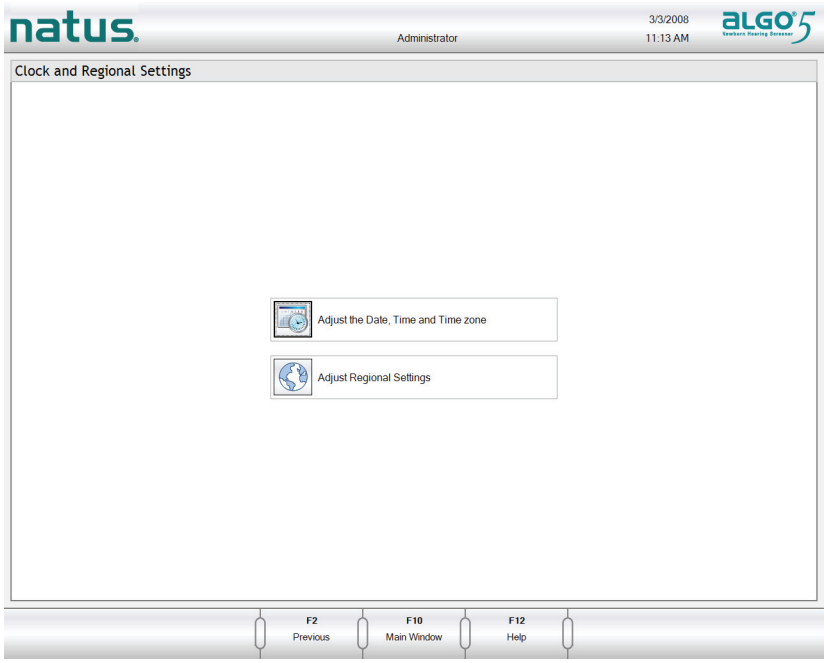
> **Note:** Only specific models of letter-size printers recommended by Natus Medical can be used or supported.

Date and Time Control

The time and date appear on the results printout. The time on the printout is always in 24-hour format, regardless of how you enter the time into the screener. The internal clock is maintained by a battery, so time normally does not need to be reset when you unplug the screener.

To access this window, select **Date, Time, Timezone, and Regional Settings** from the System Control window. The following window will appear:

Figure 48—Clock and Regional Settings window



To adjust the date, time, and timezone:

1 **Select Adjust the Date, Time, and Time zone from the Clock and Regional Settings window.**

2 **Edit the date and time information in the Date & Time tab.**

3 **Edit the time zone information in the Time Zone tab.**

4 **Select whether or not you would like the screener to automatically synchronize with an Internet time server in the Internet Time tab.**

5 **When you have finished entering your changes, select OK.**

To adjust the regional settings:

1 **Select Adjust Regional Settings from the Clock and Regional Settings window.**

2 **Use the tabs to enter the appropriate regional settings information.**

3 **When you are finished entering your changes, select OK.**

Wireless LAN

The Wireless LAN window your ALGO 5 screener to communicate through an existing wireless network at your healthcare facility using DHCP only.

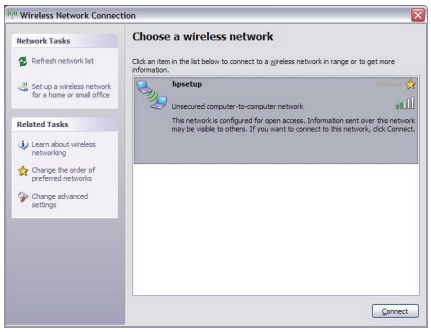
A wired LAN is also available, using the ethernet port on the back of the computer/monitor. No settings are configurable on the ALGO 5 for wired LAN.

IP addresses are not assignable in either wireless or wired settings on the ALGO 5.

 © 2011 Natus Medical Incorporated

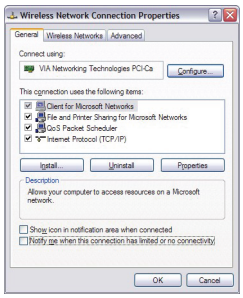
To access this function, select **Wireless LAN** from the System Control window. The following dialog box will appear:

Figure 49—Wireless LAN dialog box


Wireless Network Connection
Network Tasks
Refresh network list
Set up a wireless network for a home or small office
Related Tasks
Learn about wireless networking
Change the order of preferred networks
Change advanced settings
Choose a wireless network
Click an item in the list below to connect to a wireless network in range or to get more information.
hpsetup
Unsecured computer-to-computer network
This network is configured for open access. Information sent over this network may be visible to others. If you want to connect to this network, click Connect.
Connect

Click on the Properties tab, and the following dialog box will appear:

Figure 50—Setting wireless LAN properties



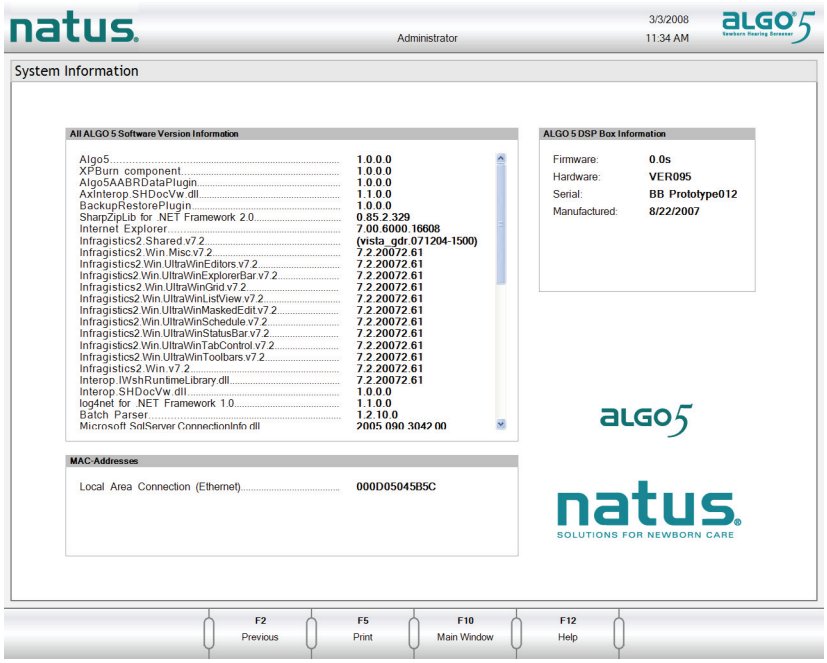
IMPORTANT: The wireless LAN settings should only be configured by someone knowledgeable about the specific wireless systems at your health facility.

System Info

The System Info window lists information about the device, including software versions, MAC addresses, and baseboard information such as firmware and hardware versions, serial number, and manufacture date. Natus Medical Technical Service or your authorized service provider may request this information during a service call.

To access this window, select **System Info** from the System Control preferences window. The following window will appear:

Figure 51—System Information window



Update

Use the Update window to update the ALGO 5 to the latest version, as provided to you by Natus Medical Technical Service or your authorized service provider.

To access this window, select **Update** from the System Control window.

Backup

Use the Backup window to run a backup of the data stored on your ALGO 5 screener. The default backup location will be displayed, if one has been set up, or an alternate location for the backup file can be entered manually.

For more information on setting up a default backup location, see “Export Format and Network Settings” on page 101.

To access this window, select Backup from the System Control window.

To run a backup of your ALGO 5 data:

1 **Select the preferred backup location, either the default if it has been entered or an alternate location.**

2 **Select Start Backup (F1).**

3 **When the backup has been completed, you may choose Previous (F2) to return to the System Control window, or Main Window (F10) to return to the Main Window.**

 © 2011 Natus Medical Incorporated

Restore

Use the Restore window to restore the database from a previous backup file. The administrator can set up a default remote location from which to import the backup data file, or an alternate location can be entered manually.

For more information on setting up a default remote location for the backup file, see "Export Format and Network Settings" on page 101.

To access this window, select **Restore** from the System Control window.

To restore from a backup data file:

1 **Highlight the drive where the backup data file is stored. A list of available data files will appear in the box below the list of drives.**

2 **Highlight one of the backup files, then select Start Restore (F1).**

3 **When the data restoration is complete, you may choose Previous (F2) to return to the System Control window, or Main Window (F10) to return to the Main Window.**

Archive Data

ALGO 5 provides a new feature that allows you to archive data that is no longer needed for review on the device. Removing data from the database helps simplify your database, which provides improvements such as the following:

- reduces search results for common surnames
- clears the database for easier sorting or exporting
- reduces the patient information stored on your screener for data security reasons
- any other uses that benefit from having fewer patients stored on the device

Once archived, patient data cannot be imported back into the ALGO 5 database. Archived data can be viewed only by using the Analyzer Tool.

Difference between Backup and Archive

The Backup function makes a copy of your data in an external location while retaining the data on the ALGO 5 device. The new Archive function moves the data to an external location and removes those records from the device.

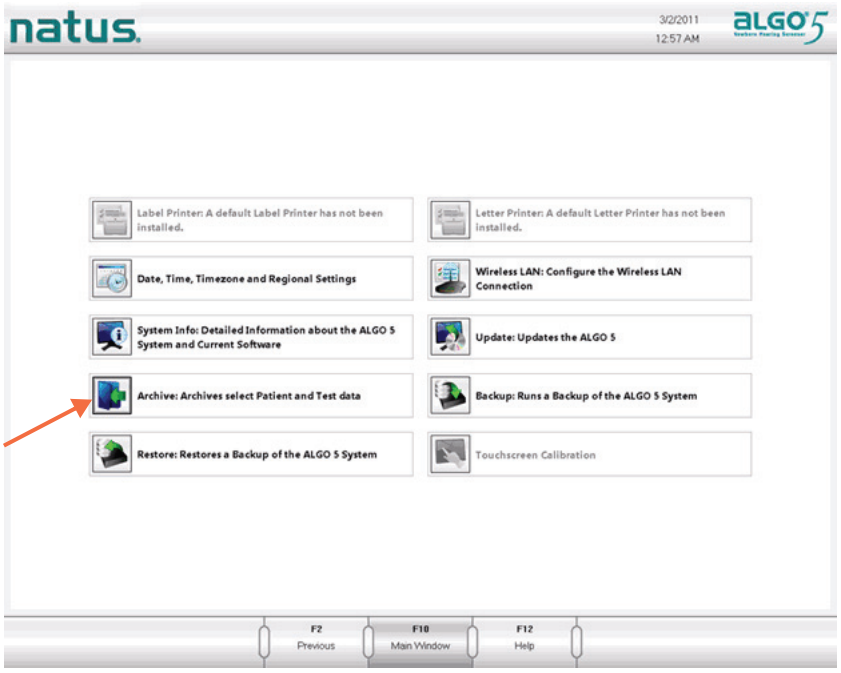
> **Note:** If you want to archive to a remote network location, first review the set-up instructions for that process at the end of this section.

To archive data to an external location:

1 **Log in as Administrator (or as a user with Administrator access), select Preferences, and then select System Control.**

The following window will appear:

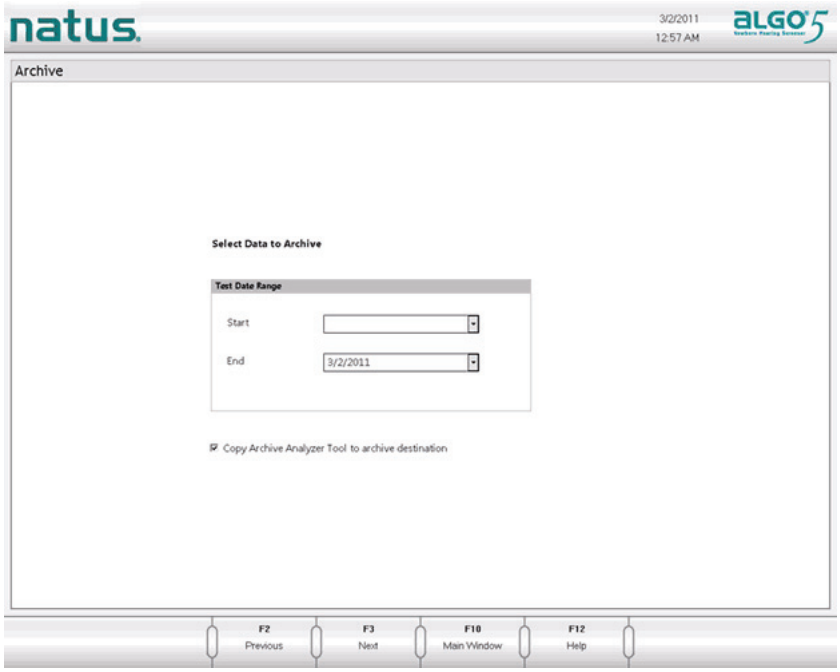
Figure 52—System Control window


natus
3/2/2011
12:57 AM
ALGO 5
Label Printer: A default Label Printer has not been installed.
Letter Printer: A default Letter Printer has not been installed.
Date, Time, Timezone and Regional Settings
Wireless LAN: Configure the Wireless LAN Connection
System Info: Detailed Information about the ALGO 5 System and Current Software
Update: Updates the ALGO 5
Archive: Archives select Patient and Test data
Backup: Runs a Backup of the ALGO 5 System
Restore: Restores a Backup of the ALGO 5 System
Touchscreen Calibration
F2 Previous
F10 Main Window
F12 Help

2 Select Archive: Archives select Patient and Test data.

The following window will appear:

Figure 53—Archive: Select Data to Archive window



 © 2011 Natus Medical Incorporated

3 Select a start date and an end date to set the date range you want.

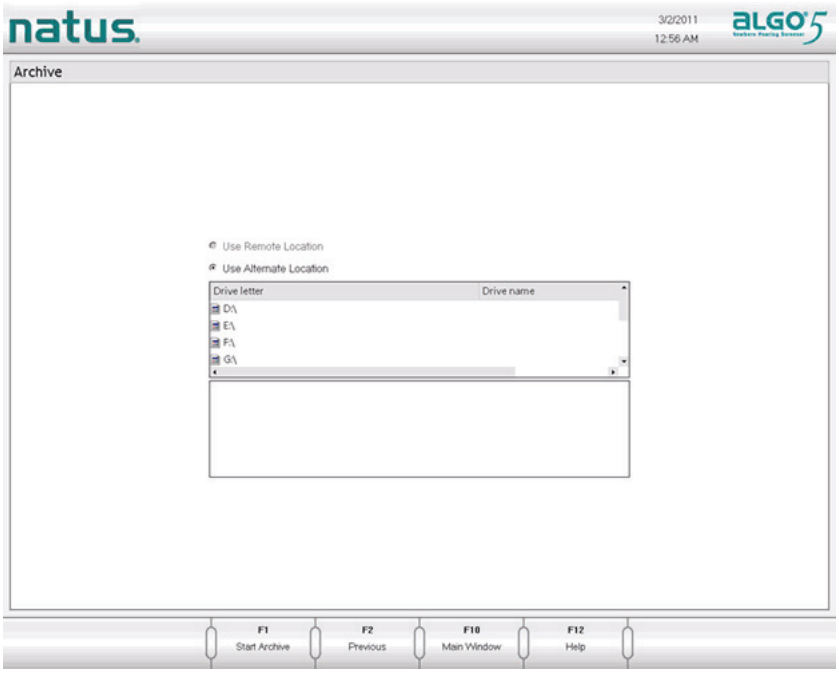
All the patient data with a test date within the range you specified will be archived and the data will be removed from the device.

An Archive Analyzer Tool utility will also be stored in the same location by default. This tool is a simple, small utility that allows you to review the patient data in a stored archive. You can use the tool to select data and copy it to a spreadsheet program or a similar program for further use.

4 Select select F3 — Next.

The following window will appear:

Figure 54—Archive: Select Location Window



5 Select the drive letter for the external location for the archive. The location can be media, such as a CD-R disc or a USB flash drive.

Note: The **Use Remote Location** setting is for networked drives. Before archiving to a network location, review the network settings for archiving. See the following procedure for instructions on reviewing network settings for archiving.

6 Select F1 — Start Archive.

The ALGO 5 screener will begin to create the archive and display status indicators.

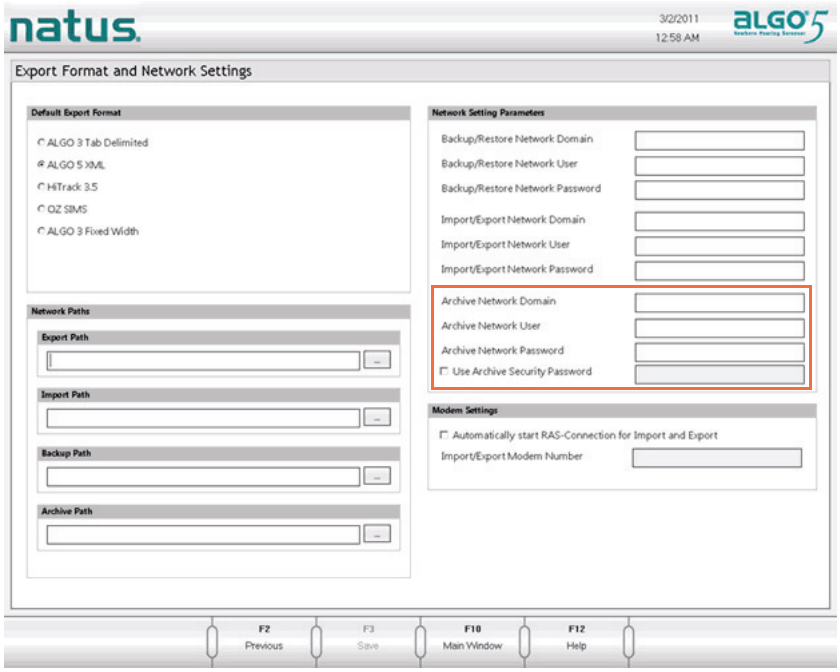
To verify network settings for archiving:

Note: The **Use Remote Location** setting is for networked drives. Before archiving to a network location, review the network settings for archiving.

1 **Select Preferences > Data Management Preferences > Export Format and Network Settings.**

The following window with the new Archive settings (highlighted) will appear.

Figure 55—Export Format and Network Settings Window



2 **Type in the following information:**

- Network domain
- Network user ID
- Network password

This information is specific to your hospital and you may need to consult your IT or IS department.

3 **Select Use Archive Security Password to set a password to protect the archive file after it is saved. If you set an archive password, you need to use the password to view the archived data. Save the password in a safe location.**

 © 2011 Natus Medical Incorporated

audble® Data Management

The ALGO 5 screener includes built-in data management software. The data management software included with this screener is one of the “audble” family of data management products developed by Natus Medical. The software retrieves and displays data stored in the hearing screener or imported from a data file. Screening results are automatically available to the data management module. Patient and test data from several ALGO 5 screeners can be combined on one ALGO 5 device for viewing, editing, and reporting.

Regular users can use the software to:

- View screening records: see “Finding and Displaying Patient Records” on page 115
- Edit or add patient records: see “Editing Patient Records” on page 117 and “Adding Patient Records” on page 118
- Export data to other database formats used by your healthcare facility for editing or data management: see “Exporting Data” on page 118
- Import data from various data files and devices: see “Importing Data” on page 120
- Select and print letters and reports: see “Selecting and Printing Letters and Reports” on page 122
- Customize the data display: see “Customizing Data Display” on page 124

Note on Configuration

Because the data management software is customizable, some of the screens and reports shown in this manual may look slightly different on your system. You may have access to additional features, or your access may be restricted, depending on how the software was configured by your administrator.

Example Data

Throughout this manual, you will find screen shots that illustrate the windows you see when using the data management software. In some cases, these screen shots appear to contain patient data. This data is fictional, having been created for illustration purposes only.

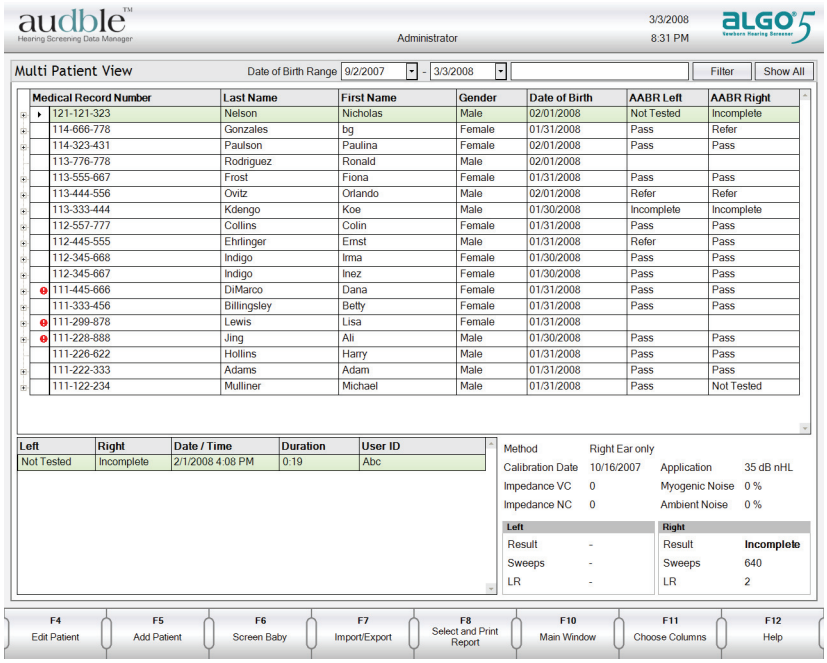
Finding and Displaying Patient Records

By default, the Multi Patient View window shows all available records. You can narrow this selection by displaying records within a defined Date of Birth range, or by filtering for individual or groups of records.

1 Select Data Management (F3) from the Main window.

The Multi Patient View window appears, shown below:

Figure 56—Multi Patient View window


audble
Hearing Screening Data Manager
Administrator
3/3/2008
8:31 PM
ALGO 5
Multi Patient View
Date of Birth Range 9/2/2007 - 3/3/2008
Filter
Show All
Medical Record Number | Last Name | First Name | Gender | Date of Birth | AABR Left | AABR Right
121-121-323 | Nelson | Nicholas | Male | 02/01/2008 | Not Tested | Incomplete
114-666-778 | Gonzales | bg | Female | 01/31/2008 | Pass | Refer
114-323-431 | Paulson | Paulina | Female | 02/01/2008 | Pass | Pass
113-776-778 | Rodriguez | Ronald | Male | 02/01/2008
113-555-667 | Frost | Fiona | Female | 01/31/2008 | Pass | Pass
113-444-556 | Ovitz | Orlando | Male | 02/01/2008 | Refer | Refer
113-333-444 | Kdengo | Koe | Male | 01/30/2008 | Incomplete | Incomplete
112-557-777 | Collins | Colin | Female | 01/31/2008 | Pass | Pass
112-445-555 | Ehrlinger | Ernst | Male | 01/31/2008 | Refer | Pass
112-345-668 | Indigo | Irma | Female | 01/30/2008 | Pass | Pass
112-345-667 | Indigo | Inez | Female | 01/30/2008 | Pass | Pass
111-445-666 | DiMarco | Dana | Female | 01/31/2008 | Pass | Pass
111-333-456 | Billingsley | Betty | Female | 01/31/2008 | Pass | Pass
111-299-878 | Lewis | Lisa | Female | 01/31/2008
111-228-888 | Jing | Ali | Male | 01/30/2008 | Pass | Pass
111-226-622 | Hollins | Harry | Male | 01/31/2008 | Pass | Pass
111-222-333 | Adams | Adam | Male | 01/31/2008 | Pass | Pass
111-122-234 | Mulliner | Michael | Male | 01/31/2008 | Pass | Not Tested
Left | Right | Date / Time | Duration | User ID
Not Tested | Incomplete | 2/1/2008 4:08 PM | 0:19 | Abc
Method Right Ear only
Calibration Date 10/16/2007 Application 35 dB nHL
Impedance VC 0 Myogenic Noise 0 %
Impedance NC 0 Ambient Noise 0 %
Left
Result -
Sweeps -
LR -
Right
Result Incomplete
Sweeps 640
LR 2
F4 Edit Patient
F5 Add Patient
F6 Screen Baby
F7 Import/Export
F8 Select and Print Report
F10 Main Window
F11 Choose Columns
F12 Help

2 Medical records are displayed as a list, displayed in descending medical record number (MRN) order.

Each individual record is displayed on one line. The default setting displays the MRN, last name, first name, gender, date of birth, and left- and right-ear test results for each individual record.

3 To re-order the records by different columns, click on the column title.

For instance, to display the patient records in order of birth date, click on "Date of Birth."

Note: This display is customizable, and different columns may appear in your version of the software, depending on the parameters defined by your administrator.

4 A " ! " in the column to the left of a patient's name indicates that the patient has one or more risk factors.

Select the "+" symbol to the left of an individual record in the list to display the patient's risk factors.

5 To view or edit a full individual record:

a Highlight the record and select **Edit Patient (F4)**, or double-click anywhere in the row of an individual record.

b When you are done viewing or editing the record, select **Return to All Patients (F5)** to return to the Multi View window.

 © 2011 Natus Medical Incorporated

c For more information on entering patient data, see “Enter Patient Information” on page 35. For more information on editing patient data, see “Editing Patient Records” on page 117

6 To narrow the list by Date of Birth range, fill in the two date fields.

There are two methods for inputting dates into the field:

a Type the dates into the fields using the keyboard, or

b Use the pointing device to click on the arrow, which brings up an interactive calendar

7 Search by first or last name, MRN, or test result.

Type the query data into the text box in the top right corner of the screen, and select “**Filter**.”

Note: You do not need to enter complete data for searching. Enter partial field data, such as the first few letters of a name or a few characters of the MRN, and then select **Search Patients (F3)**. This will bring up a filtered list from which you can select the individual patient record.

Editing Patient Records

To edit individual records:

1 Find an individual patient record as described in “Finding and Displaying Patient Records” on page 115**.**

2 Highlight the record and select Edit Patient (F4) or double-click anywhere in the row for that record.

3 Enter or change patient data.

See “Enter Patient Information” on page 35 for detailed instructions on entering patient data.

- In some cases, fields such as MRN are read-only and cannot be edited.
- When entering a **Pediatrician**, you can either type in the doctor’s name, or select the name from the list.
- You can enter multiple **Risk Factors**. When you select one from the listbox, it will be added to the box of selected Risk Factors. To add another one, simply choose it from the list.
- You cannot change Test Result information.

4 Select Undo All Changes (F9) to return to the previously saved patient information.

5 Select Save Patient (F3) when you are finished correctly entering or changing the patient data.

Once you have saved your edited patient data, you may no longer return to the previous version of the record.

Note: If you edit a patient but move to another screen without selecting **Save Patient**, your edits will not be saved.

6 **Select Back to All Patients (F5) to return to the Multi Patient View window.**

Adding Patient Records

You can add patient records from the data management module, for instance, to prepopulate a list of patients to be screened. To add new individual records:

1 **Select Add Patient (F5) from the Multi Patient View window.**

2 **Enter patient data**

See "Enter Patient Information" on page 35 for detailed instructions on entering patient data.

3 **Select Undo All Changes (F9) to delete all the information that you entered.**

4 **Select Save Patient (F3) when you are finished correctly entering the patient data.**

5 **Select Back to All Patients (F5) to return to the Multi Patient View window.**

Screen Baby

You may also screen a baby selected in the Multi Patient View window.

1 **Find an individual patient record or group of records as described in** "Finding and Displaying Patient Records" on page 115**.**

2 **Select a patient, then select Screen Baby (F6).**

3 **Proceed with screening as described in** "Preparing the Baby for Screening" on page 39 **and** "Running the Screening Procedure" on page 45**.**

Exporting Data

If desired, selected patient records can be exported in a variety of data formats. including ALGO 5, OZ and HiTrack formats. A default format must be set in the Data Management preferences. (See "Export Format and Network Settings" on page 101 for more information.) The export files from the ALGO 5 screener are text-based and unencrypted.

To export data:

1 **From the Multi Patient View window, choose the records to be exported by clicking in the individual record row.**

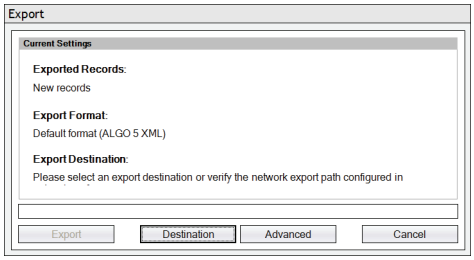
To choose multiple records, press CTRL while clicking on each record.

2 **Select Import/Export (F7), then select Export.**

3 **If default export format and destination settings have been entered, they will appear in the Export Settings dialog box, shown below:**

 © 2011 Natus Medical Incorporated

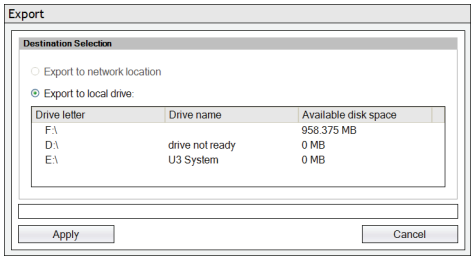
Figure 57—Export Settings dialog box



See “Export Format and Network Settings” on page 101 for more information on entering default format and destination settings.

4 Select Destination. Verify or enter a destination for the exported data file in the Destination Selection dialog box, shown below:

Figure 58—Destination Selection dialog box



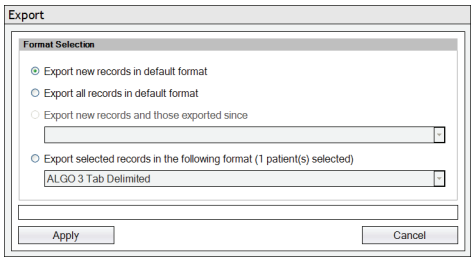
Select **Apply** to return to the Export Settings dialog box.

Note: The Export button will be unavailable (grayed out) until a destination has been entered or verified.

Note: You may export to a network drive, removable media (such as a USB thumb drive), or burn to a CD. CD burning is multi-session; you may continue to use the same CD until the capacity is reached.

5 To enter an alternate export format, select Advanced. Enter your preferred format in the Format Selection dialog box, shown below:

Figure 59—Format Selection dialog box


Export
Format Selection
Export new records in default format
Export all records in default format
Export new records and those exported since
Export selected records in the following format (1 patient(s) selected)
ALGO 3 Tab Delimited
Apply
Cancel

Select **Apply** to return to the Export Settings dialog box.

6 **When you have finished entering your settings, select Export.**

7 **A dialog box will appear informing you of the number of records that were exported.**

Note: Depending on the export format chosen, the number of records exported may refer to the number of tests. If the information for a patient has been entered, but no tests have been performed on that patient, the patient's record will not be exported. It is possible for no records to be exported even if patients have been selected.

Importing Data

Use the Import function to import patient records from a data file created on other ALGO 5 devices or from hospital data systems formatted to comply with the ALGO 5 XML data format.. This is useful, for example, to consolidate a patient's screens done on different devices into a single record, or to combine data from all devices for the purpose of tracking statistics.

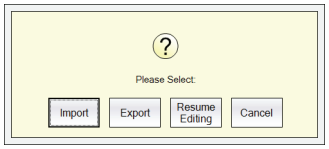
Note: The Import Data function is only available to users with administrator-level status, or as defined in a custom profile by your system administrator.

A default network import location may be set in Data Management preferences. (See "Export Format and Network Settings" on page 101 for more information). You may also enter an import location manually at the time of each import.

To import data:

1 **From the Multi Patient View window, choose Import/Export (F7), then select "Import" from the following dialog box:**

Figure 60—Import/Export dialog box

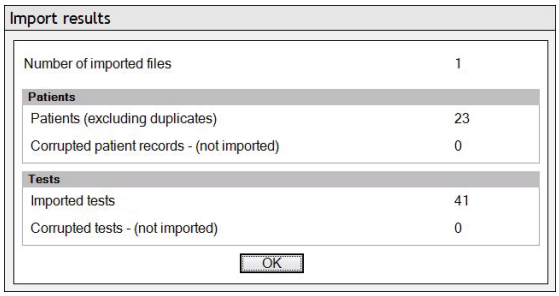


2 **The default settings for network import location will be displayed in the import dialog box.**

An alternate location can be manually entered. Multiple import files may be selected by holding down the "CTRL" key. The following window will appear:

 © 2011 Natus Medical Incorporated

Figure 61—Import results window



3 The Import Results window provides the following information:

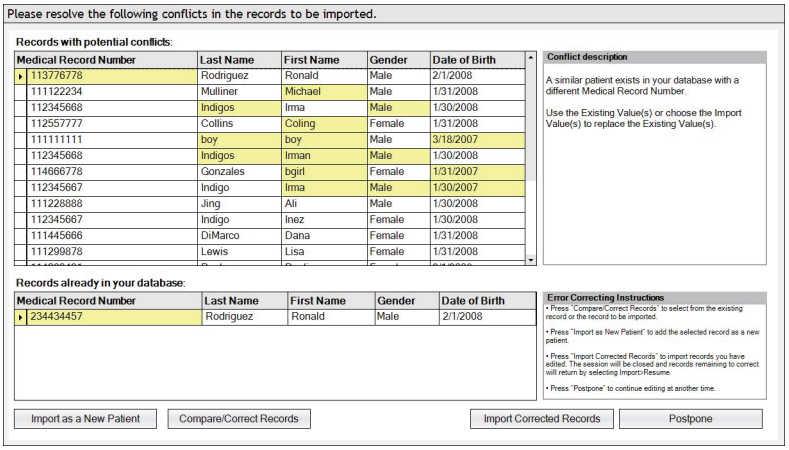
- how many patient records and tests will be imported
- whether there are any conflicting records
- whether there are any corrupted (unimportable) data

Records that do not occur on the ALGO 5 will be imported and added to the database. Records that are additional information to an existing record on the device are appended to the existing record.

Resolving Import Conflicts

If there are any records with potential conflicts, the software will prompt you to correct the errors. The following window will appear:

Figure 62—Import Conflicts window


Please resolve the following conflicts in the records to be imported.
Records with potential conflicts:
Medical Record Number | Last Name | First Name | Gender | Date of Birth
113776778 | Rodriguez | Ronald | Male | 2/1/2008
111122234 | Mulliner | Michael | Male | 1/31/2008
112345668 | Indigos | Irma | Male | 1/30/2008
112557777 | Collins | Coling | Female | 1/31/2008
111111111 | boy | boy | Male | 3/18/2007
112345668 | Indigos | Irman | Male | 1/30/2008
114666778 | Gonzales | bgirl | Female | 1/31/2007
112345667 | Indigo | Irma | Male | 1/30/2007
111228888 | Jing | Ali | Male | 1/30/2008
112345667 | Indigo | Inez | Female | 1/30/2008
111445666 | DiMarco | Dana | Female | 1/31/2008
111299878 | Lewis | Lisa | Female | 1/31/2008
Conflict description
A similar patient exists in your database with a different Medical Record Number.
Use the Existing Value(s) or choose the Import Value(s) to replace the Existing Value(s).
Records already in your database:
Medical Record Number | Last Name | First Name | Gender | Date of Birth
234434457 | Rodriguez | Ronald | Male | 2/1/2008
Error Correcting Instructions
• Press "Compare/Correct Records" to select from the existing record or the record to be imported.
• Press "Import as New Patient" to add the selected record as a new patient.
• Press "Import Corrected Records" to import records you have edited. The session will be closed and records remaining to correct will return by selecting Import>Resume.
• Press "Postpone" to continue editing at another time.
Import as a New Patient
Compare/Correct Records
Import Corrected Records
Postpone

To correct conflicts:

1 Highlight an incoming record in the "Records with potential conflicts" area by clicking anywhere in the line for that record.

- An arrow in the left column indicates that the record is selected.
- The current existing record information appears in the "Records already in your database" area.

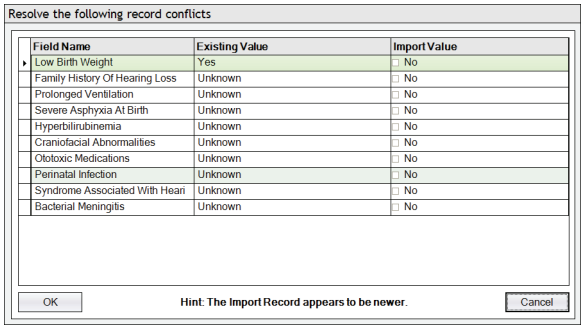
2 **Refer to the "Conflict Description" area in the upper right for details about the conflict for the selected record and advice about how to proceed.**

3 **Select Import as New Patient to add the selected record as a new patient to your database.**

4 **Select Compare/Correct Records to view the records and select the appropriate data for each error from either the existing record or the new record to be imported.**

The following window appears:

Figure 63—Resolve conflicts dialog box



Select whether to use the existing or imported values, then select **OK**.

5 **Press "Postpone" to close this session and retain the records that still require editing for your next editing session.**

If you choose to postpone import, any changes that you made will not be saved.

6 **When you have finished with your corrections, select Import Corrected Records.**

The Error Editing grid will be closed. Records remaining to be corrected will be available again by selecting **Import / Resume** from the Data Management window.

Selecting and Printing Letters and Reports

The administrator may choose among the available letters and reports relating to either patients or statistics. Administrators can also customize existing reports and letters (see "Report Template Editor" on page 97 for detailed instructions).

 © 2011 Natus Medical Incorporated

Printing Labels

You can print a self-adhesive label suitable for the patient chart. The label will be printed on your Natus Seiko Label Printer. To print labels:

1. **Find the patient as described in the section** "Finding and Displaying Patient Records" on page 115**.**
2. **Select a test by clicking on it in the Test Results List.**
3. **Choose Select and Print Report (F8), then choose Patients, then ALGO 5 Label.**
4. **The label for the selected test will be printed.**

Printing Letters and Reports

If your ALGO 5 device includes a letter-size printer, you may also print letters and reports. To print letters:

1. **Find the patient (or multiple patients) as described in the section** "Finding and Displaying Patient Records" on page 115**.**
2. **Select a patient from the list. Select multiple patients by holding down the "CTRL" key.**
3. **Choose Select and Print Report (F8), choose either Patients or Statistics, then select which letter or report you'd like to print.**

   For a list of letters and reports in each category, see "Patients Reports and Letters" on page 123 and "Statistics Reports" on page 123.
4. **Select from the "Letter Type" pull-down menu, if applicable, then select Print.**

Patients Reports and Letters

- **Letters to the Parents:** Passed, Missed, or Pass with Risk Factors
- **Refer to Audiologist**
- **Letter to the Doctor:** Pass or Refer
- **Follow Up Required**
- **Waiver**
- **ALGO 5 Label or Letter (report):** all tests or selected tests
- **Multiple Patients List**

Statistics Reports

- **Patient Statistics:** from a defined date range
- **User Statistics:** for all users or a single user from a defined date range

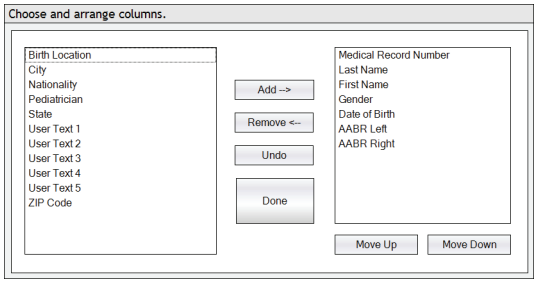
Customizing Data Display

The default data display configuration shows columns for the MRN, last name, first name, gender, date of birth, and AABR left and right for the list of patients. You may customize this configuration by adding or deleting columns or by changing the order in which they are displayed.

To customize the data display:

1 **From the Multi Patient View window, select Choose Columns (F11). This will bring up the following dialog box:**

Figure 64—Choose columns dialog box



2 **To add columns to the display:**

a Highlight an item from the list on the left, and then

b Select "**Add >**"

Note: Hold down the "Ctrl" key on the keyboard to select more than one item at a time.

3 **To remove columns from the display:**

a Highlight an item from the list on the right.

b Select "**Remove <**"

4 **To change the order in which the columns are displayed:**

a Highlight an item in the list on the right.

b Select "**Move Up**" or "**Move Down**" to change the display order.

5 **To remove all changes that you have made and return to the default display, select "Default."**

6 **When you are finished with your changes, select "Done." The Multi Patient View window will now reflect the changes you made.**

 © 2011 Natus Medical Incorporated

Appendix 1

Storing ALGO 5 Screener Cables

The ALGO 5 Newborn Hearing Screener gives you a variety of different ways to store the device's cables. Storing the sensor cable (PCA 5), preamplifier 5 cable, and earphone cable (ATA 5), protects the cable components from damage.

The cables may be stored in any of the following ways:

- Draped over the cable hanger assembly at the back of the cart.
- Inside the drawer under the keyboard tray.
- On the first shelf directly below the drawer.

The power cord may be coiled loosely and draped around the top of the column behind the monitor display.

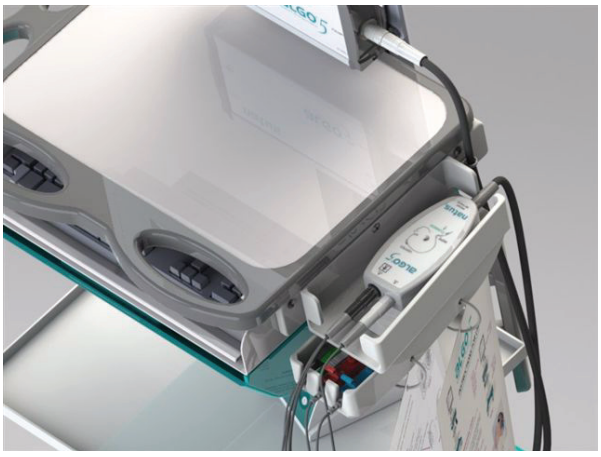
Natus advises you to store the cable ends (those that contact the supplies) in a manner so as to provide them protection from accidental impact.

a) They can be stored on the back of the device **by hanging the ends on the forked metal bracket**.

b) The ends can also be **brought around to the front of the device and placed into the drawer**. (Care should be taken to ensure that the cables are not caught in the drawer runners if this method is used.)

Natus is also providing an additional storage option of an attachable tray for the storage of the PreAmp body and the PCA and ATA cables.

Figure 65—Attachable tray for storing PreAmp body and PCA and ATA cables



This tray can be attached to the side of your ALGO 5 cart and will serve as an additional option for protection and storage of the sensitive components. See the installation instructions included with the tray.

High Risk Indicators

There are several high-risk indicators associated with hearing loss. On the Patient Information Window, you can select the high-risk indicators that apply to the patient being screened. These high-risk indicators were established by the Joint Committee on Infant Hearing.

Note: You should identify the high-risk indicators that apply to a particular patient according to the protocol of your healthcare facility. There may be additional high-risk indicators associated with hearing loss that the ALGO screener does not provide. Consult your healthcare facility's protocol to ensure that you identify the appropriate high-risk indicators.

- Caregiver concern
- Family history of permanent childhood hearing loss
- NICU > 5days or ECMO, assisted ventilation, otoxic meds, hyperbilirubinemia requiring exchange transfusion
- In utero infections: CMV, herpes, rubella, syphilis, toxoplasmosis
- Craniofacial/temporal bone anomalies; pinna, ear canal, ear tags or pits
- Physical findings associated with hearing loss syndromes (e.g. white forelock)
- Syndromes; neurofibromatosis, osteopetrosis, Usher, Waardenberg, Alport, Pendred, Jervell & Lange-Nielson
- Neurodegenerative disorders (e.g.,Hunter) or sensory motor neuropathies (e.g., Friedreich ataxia, Charcot-Marie-Tooth)
- Culture-positive postnatal infections; confirmed baterial and viral (especially herpes and varicella) meningitis.
- Head trauma, basal skull/temporal bone fracture requiring hospitalization
- Chemotherapy

Please refer to the Joint Comission on Infant Hearing's 2007 Position Statement for complete details.

Specifications

Note: Specifications are subject to change without notice.

Sweep Rates

- 37 clicks/second (nominal) or 34 clicks/second (nominal) alternating

Power Supply

- Power Rating100-120 V~, or 200-240 V~100 VA, 50/60 Hz

This system complies with the following safety and EMC standards: UL2601-1; CSA-22.2 601-1; FDA 92-4158; EN60601-1 and EN60601-1-2 Class I, Type BF Equipment.

 © 2011 Natus Medical Incorporated

Classifications

- Class I equipment, BF type applied part
- Ordinary equipment for protecting against ingress of water
- Not suitable for use in the presence of flammable Anaesthetic Mixture with Air, Oxygen or Nitrous Oxide
- Continuous operation
- Operating Temperature: 10° - 40° C (50° - 104° F)
- Storage Temperature: -20° - 40° C (-4° - 104° F)
- Humidity Range:10 - 90% non-condensing
- Operating Altitude:sea level - 6000 ft

Glossary

auditory brainstem response (ABR): Electrical brain wave activity originating from the auditory brainstem in response to an external stimulus such as a click sound from the screener's transducers.

conductivity: The ability to transmit electrical current.

dB nHL: A scale for measuring sound intensity, with a biological reference level (instead of absolute sound pressure level).

fontanel: A gap between bones covered with skin and other membranes, in particular, on an infant's head.

impedance: Opposition to the flow of electrical current.

nape: Back of the neck

sweep count: The number of "acceptable" sweeps accumulated by the screener. A single sweep is one instance in which the screener generates a click and collects usable data in response to the click.

tragus: The prominence in front of the external opening of the ear.

transducer: A device designed to convert electrical energy into acoustical energy and vice versa; for example, a microphone or speaker.

vernix: Sebacious deposits covering the fetus; exfoliated outer skin, hair, and secretions from oil glands.

vertex: The vertex sensor is placed on the high forehead.

 © 2011 Natus Medical Incorporated

Appendix 2

ALGO 5 Software License Agreement

PLEASE READ THE FOLLOWING TERMS AND CONDITIONS CAREFULLY BEFORE USING THE SOFTWARE (DEFINED BELOW) OR ANY ACCOMPANYING DOCUMENTATION (DEFINED BELOW).

THE TERMS AND CONDITIONS OF THIS SOFTWARE LICENSE AGREEMENT ("AGREEMENT") GOVERN YOUR USE OF THE SOFTWARE UNLESS YOU AND NATUS MEDICAL INCORPORATED ("NATUS") HAVE EXECUTED A SEPARATE AGREEMENT.

audble™ Data Management Software is integrated with and pre-installed on your new ALGO 5 Hearing Screening System and cannot be uninstalled nor installed on any other device. It is a component of your screening system required for the operation of the screener and management of your patient and test data.

Natus is willing to license the Software to you only upon the condition that you accept all the terms contained in this Agreement. If you use the Software or keep it for 30 days after the date of purchase, then you have indicated that you understand this Agreement and accept all of its terms. If you do not accept all the terms of this Agreement, then Natus is unwilling to license the Software to you.

1. Grant of License. Subject to your compliance with the terms and conditions of this Agreement, Natus grants you a perpetual, non-exclusive and non-transferable license to use the Object Code, and any Updates, on ALGO 5 Hearing Screeners located at your buildings or facilities solely for your internal business purposes. "Object Code" means the fully compiled version of the software described in the user guide(s) accompanying this Agreement (the "Documentation") that can be executed by a computer and used by an end user without further compilation (such software and Documentation collectively comprising the "Software"). "Updates" means modifications made by Natus to the Software, that Natus generally makes available at no additional charge to its customers when Natus has determined, at Natus' sole discretion, to release a periodic software update. The number of concurrent users of the system cannot exceed the number of ALGO 5 Systems that have audble preinstalled. Natus reserves all rights in the Software not expressly granted to you in this Agreement.

2. Restrictions. Except as expressly specified in this Agreement, you may not: (a) copy or modify the Software or (b) transfer, sublicense, lease, lend, rent or otherwise distribute the Software to any third party. You acknowledge and agree that portions of the Software, including, without limitation, the source code and the specific design and structure of individual modules or programs, constitute or contain trade secrets of Natus and its licensors. Accordingly, you agree not to disassemble, decompile or otherwise reverse engineer the Software, in whole or in part, or permit or authorize a third party to do so, except

to the extent such activities are expressly permitted by law notwithstanding this prohibition.

3. Ownership. The Software is licensed, not sold. You own the media on which the Software is recorded, but Natus retains ownership of the Software, including all intellectual property rights therein. The Software is protected by United States copyright law and international treaties. You will not delete or in any manner alter the copyright, trademark, and other proprietary rights notices or markings appearing on the Software as delivered to you.

4. Term. This Agreement remains effective until terminated. You may terminate it at any time by destroying all copies of the Software in your possession or control. This Agreement will automatically terminate without notice if you breach any term of this Agreement. Upon termination, all licenses granted hereunder will immediately terminate and you must promptly destroy all copies of the Software in your possession or control.

5. Limited Warranty. Natus warrants that for thirty (30) days following the date of purchase, the media on which the Software or subsequent Software Updates are provided will be free from defects in materials and workmanship under normal use. As your sole and exclusive remedy and Natus' entire liability for any breach of this limited warranty, Natus will promptly replace the defective media, at no charge.

6. DISCLAIMER. THE LIMITED WARRANTY SET FORTH IN SECTION 5 IS IN LIEU OF, AND NATUS EXPRESSLY DISCLAIMS, ALL OTHER WARRANTIES AND CONDITIONS, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES AND CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT, AND ANY WARRANTIES AND CONDITIONS ARISING OUT OF COURSE OF DEALING OR USAGE OF TRADE. NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED FROM NATUS OR ELSEWHERE WILL CREATE ANY WARRANTY OR CONDITION NOT EXPRESSLY STATED IN THIS AGREEMENT. Some jurisdictions do not allow limitations on how long an implied warranty last, so the above limitation may not apply to you. All warranties implied by statute are limited to the duration of the express warranty set forth above. This warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction.

7. Limitation of Liability. NATUS'S TOTAL LIABILITY TO YOU FROM ALL CAUSES OF ACTION AND UNDER ALL THEORIES OF LIABILITY WILL BE LIMITED TO AND WILL NOT EXCEED THE AMOUNTS PAID TO NATUS BY YOU FOR THE SOFTWARE. IN NO EVENT WILL NATUS BE LIABLE TO YOU FOR ANY SPECIAL, INCIDENTAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF USE, DATA, BUSINESS OR PROFITS) OR FOR THE COST OF PROCURING SUBSTITUTE PRODUCTS ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE USE OR PERFORMANCE OF THE SOFTWARE, WHETHER SUCH LIABILITY ARISES FROM ANY CLAIM BASED UPON CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, AND WHETHER OR NOT NATUS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE. THE FOREGOING LIMITATIONS WILL SURVIVE AND APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THIS AGREEMENT IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. Some

 © 2011 Natus Medical Incorporated

jurisdictions do not allow the limitation or exclusion of liability for incidental or consequential damages, so the above limitation or exclusion may not apply to you.

8. Confidentiality

8.1. Definition. "Confidential Information" means: (a) the Software and (b) any business or technical information of Natus that, if disclosed in writing, is marked "confidential" or "proprietary" at the time of disclosure, or, if disclosed orally, is identified as "confidential" or "proprietary" at the time of disclosure, and is summarized in a writing sent by Natus to you within thirty (30) days of such disclosure.

8.2. Exclusions. Confidential Information does not include information that: (a) is or becomes generally known to the public through no fault of or breach of this Agreement by you; (b) is rightfully known by you at the time of disclosure without an obligation of confidentiality; (c) is independently developed by you without use of the Confidential Information; or (d) you rightfully obtain from a third party without restriction on use or disclosure.

8.3. Use and Disclosure Restrictions. You will not use the Confidential Information except as necessary for the performance of this Agreement and will not disclose such Confidential Information to any third party except to those of your employees and subcontractors that need to know such Confidential Information for the purpose of performing this Agreement, provided that each such employee and subcontractor is subject to a written agreement that includes binding use and disclosure restrictions that are at least as protective as those set forth herein. You will use all reasonable efforts to maintain the confidentiality of all such Confidential Information in your possession or control, but in no event less than the efforts that you ordinarily use with respect to your own proprietary information of similar nature and importance. The foregoing obligations will not restrict you from disclosing Confidential Information: (a) pursuant to the order or requirement of a court, administrative agency, or other governmental body, provided that you give reasonable notice to Natus to contest such order or requirement; or (b) on a confidential basis to your legal or financial advisors.

9. Government Users. The Software and Documentation are "commercial computer software" and "commercial computer software documentation", respectively, as such terms are used in FAR 12.212. Any use, duplication or disclosure of the Software or the Documentation by or on behalf of the U.S. Government is subject to restrictions as set forth in this Agreement. Manufacturer is Natus Medical Incorporated.

10. Export Law. You agree to comply fully with all U.S. export laws and regulations to ensure that neither the Software nor any technical data related thereto, nor any direct product thereof, are exported or re-exported directly or indirectly in violation of, or used for any purposes prohibited by, such laws and regulations.

11. General. This Agreement will be governed by and construed in accordance with the laws of the State of California, without regard to or application of conflicts of law rules or principles. The United Nations Convention on Contracts for the International Sale of Goods will not apply. You may not assign or transfer this Agreement or any rights granted hereunder, by operation of law or otherwise, without Natus' prior written consent, and any attempt by you to do

so, without such consent, will be void and of no effect. Except as expressly set forth in this Agreement, the exercise by either party of any of its remedies under this Agreement will be without prejudice to its other remedies under this Agreement or otherwise. All notices or approvals required or permitted under this Agreement will be in writing and delivered by confirmed facsimile transmission, by overnight delivery service, or by certified mail, and in each instance will be deemed given upon receipt. All notices or approvals will be sent to the addresses set forth in the applicable ordering document or invoice or to such other address as may be specified by either party to the other in accordance with this section. The failure by either party to enforce any provision of this Agreement will not constitute a waiver of future enforcement of that or any other provision. Any waiver, modification or amendment of any provision of this Agreement will be effective only if in writing and signed by authorized representatives of both parties. If any provision of this Agreement is held to be unenforceable or invalid, that provision will be enforced to the maximum extent possible and the other provisions will remain in full force and effect. This Agreement is the complete and exclusive understanding and agreement between the parties regarding its subject matter, and supersedes all proposals, understandings or communications between the parties, oral or written, regarding its subject matter. Any terms or conditions contained in your purchase order or other ordering document that are inconsistent with or in addition to the terms and conditions of this Agreement are hereby rejected by Natus and will be deemed null and of no effect. The headings in this Agreement are intended solely for convenience of reference and shall be given no effect in the construction or interpretation of this Agreement.

12. Contact Information. If you have any questions regarding this Agreement, you may contact Natus at 1501 Industrial Road, San Carlos California 94070.

 © 2011 Natus Medical Incorporated

List of Figures

Screening module and cart 11
Earphone (ATA) cable 12
Sensor cable, also called the Patient Cable Assembly 5, or PCA 5 13
Preamp cable 14
DSP box 15
Jelly Tab Sensors 16
Flexicoupler earphones 17
Login window 18
Main window 19
Patient Data window 20
Risk Factors 21
Screening Method Selection window 22
Baby Preparation window 23
Screening window 24
Preferences window 25
Equipment Check window 26
audble Data Management window 27
Help Window 28
Power switches 34
Patient Selection window 37
Screening Method Selection window 38
Electrodes 40
Clip placement 41
Standard Sensor Placement
(All tabs on Jelly Tab Sensors are oriented to baby's right side) 41
Transducers attached to earphones 44
Baby with earphones 45
Baby Preparation window 50
Using Moistened Gauze to Ease Sensor Removal 52
Attachable tray for storing PreAmp body and PCA and ATA cables 54
Equipment Check window 71
Inserting Printer Labels 81
Preferences window 85
ALGO 5 Preferences window 86
Data Management Preferences window 91
Single Patient Layout Editor 92
Layout Editor Toolbox 92
"Active" groupbox showing dotted outline and handles. 93
Risk Factor Editor 96
Report template with logo and address added 98
Report Template Editor 98
Report Template Editor: Text Formatting Bar 99
Pick List Editor 100
Export Format and Network Settings window 101
Field Label Editor window 103
User Management window 104
Profile Manager window 105
System Control window 107
Clock and Regional Settings window 108
Wireless LAN dialog box 109
Setting wireless LAN properties 109
System Information window 110
System Control window 112
Archive: Select Data to Archive window 112
Archive: Select Location Window 113
Export Format and Network Settings Window 114
Multi Patient View window 116
Export Settings dialog box 119
Destination Selection dialog box 119
Format Selection dialog box 119
Import/Export dialog box 120
Import results window 121
Import Conflicts window 121
Resolve conflicts dialog box 122
Choose columns dialog box 124
Attachable tray for storing PreAmp body and PCA and ATA cables 125

 © 2011 Natus Medical Incorporated

Index

Symbols
Command buttons 17

A
AABR 1
acoustic check 73
acoustic transducer assembly (ATA) 12
ALGO 5 Preferences 86
Ambient interference indicator bar 46
ambient noise
  rejection system 56
Artifact Check 66
artifact check 72
artifact rejection systems 56
ATA 12
  figure 12
audble® Data Management 115
auditory brainstem response (ABR) 9
Automated Auditory Brainstem Response 1

B
babies, choosing 1
baby
  attaching sensors 41
  preparation 60
  skin type 42
baby preparation window (description) 23
baby, cleaning skin 53

C
Cable Assemblies 12
Cleaning the Screener 79
Clip Placement Reversed 47
computer, using 28
Contraindications for use 1
contraindications for use 1
correct placement 41
Corruption issues 75
Customizing Data Display 124

D
data management 115
Data Management Layout Editor ??–95
  default layout 95
  fields
    Adding new 93
    deleting 93
    selecting 93
  groupboxes
    deleting 93
Database Corruption 73
DSP box
  figure 15

E
earphone cable 12
  figure 12
earphone cable, calibration 82
earphone cable, cleaning 52
earphone cable, storing 52
earphones
  attaching to transducers 44
  positioning on baby 45
Electrical Safety 3
equipment check window (description) 26
error messages
  printer error 69
  system error 69
  time limit 70
Explanation of Terminology 2
Exporting Data 118

F
Field Label Editor 102
Finding and Displaying Patient Records 115
Flexicoupler earphones 16
function keys 28

H
help window 55
help window (description) 28

I
impedance
  error messages 43
Impedance Check 65
impedance check 73
Impedance readings 46
impedance, checking readings 42
impedance, understanding 44
Import Conflicts
  resolving 121
Improper Shutdown Warnings 73
Institution I.D. 49

J
Jelly Tab sensors 16

L
Label Printer 107
label printer 7
labels

printing 123
Letter and Report Editor 97
Letter Printer 107
Likelihood Ratio and Sweep Count 88
login window (description) 18

M
main window (description) 18
maintenance procedures 79
medical record format 87
medical record format (table) 87
Multi Patient View window 115
myogenic interference 48, 65
rejection system 56
myogenic interference indicator bar 46

N
notch filter 86
NuPrep 16

P
patient cable assembly (PCA) 13
Patient Data window
customize appearance 91
patient information window (description) 20
patient information, entering 35
babies with no previous screening history 36
babies with previous screening history 36
pausing a screening 49
PCA 13
percent myogenic interference 48
Pick List Editor 100
pointing device 28
preamp cable
figure 14
Preferences 85
preferences window (description) 25
preferences, setting
ALGO5
common settings 86
screening options 87
prepping techniques 60
printer error 69
Printer Settings 89
Printing Labels 123
Printing Letters and Reports 123
Profile Manager 105
Profiles 85
create new 105
edit 106

R
radio interference 3
refer result, understanding 67
reprep method 61
reprep rule 62
right/left sequential screening method 50
Risk Factors
Adding New (preferences) 97
editing list (preferences) 96
Risk Factors Editor 95
risk factors window (description) 21
risk factors, entering (during screening) 37

S
safety information
explanation of terminology 2
precautionary information 7
Safety Information 2
Screen Duration 48
screen method selection window (description) 22
screene
calibration requirements 82
screener
checking equipment 57
checking for ambient noise problems 63
checking for myogenic interference problems 65
screening method, selecting 39
screening method, selection 38
Screening Module 10
screening options, setting 87
screening procedure 45
Pausing a Screening 49
Right/Left Sequential Screening Method 50
right/left simultaneous screening method 46
Single-Ear Screening Method 51
screening procedure, overview 31
screening sites, appropriate 1
screening window (description) 24
sensor cable 12
attaching to sensors 40
figure 13
sensor cable, cleaning 51
sensor cable, storing 51
sensors 16, 41
attaching to baby 41
attaching to cable 40
service and maintenance 79
inspecting accessory parts 80
service procedures 79
Session timeout 89
Shutdown timeout 89
Single Patient Layout Editor 91
Adding New Fields 93
Deleting Fields or Groupboxes 93
Relocating and Resizing Fields 94
Relocating and Resizing Groupboxes 94
Saving or Removing Changes 95
Selecting Fields or Groupboxes 93
Setting Field Options 94
Setting Groupbox Options 95
Understanding Tab Index Numbers 95
single-ear screening method 51
sweep 9
sweep count 49, 88
Symbols 2
System Control
Backup 110
Date and time control 107
Remote control 110
Restore 111
System info 109
Update 110
Wireless LAN 108
system error 69
system failure 69

 © 2011 Natus Medical Incorporated

T

Time 48
time limit error 70
time of Scsreen 48
touch screen 28
transducers 12, 31, 44
  attaching to earphones 44
  removing from baby 51
  set up for Equipment Check 71
  warning 45, 80
Transducers attached to earphones
  figure 44
troubleshooting
  artifact rejection systems 56
  check screener 57
  myogenic interference 65
  prepping techniques 60
  reprep method 61
  reprep rule 62
  system failure 69
  understanding a refer result 67

U

Update and Backup procedures 77
User and Session Management 88
User I.D. 49
user interface
  baby preparation window 23
  equipment check window 26
  help window 28
  login window 18
  main window 18
  patient information window 20
  preferences window 25
  risk factors window 21
  screen method selection window 22
  screening window 24
  windows 17
Users
  activate or deactivate 105
  create new 104
  editing 104

 © 2011 Natus Medical Incorporated